Table 14.3.1-19 Laboratory Tests

Parameter: Erythrocytes (10^4/uL)

Group	Time	N	Mean	SD	Min	Q1	Median	Q3	Max
KLH-2109 200 mg	Screening	143	434.5	37.9	340	412	432	457	539
	Run-in	143	423.6	36.4	303	398	419	452	533
	Baseline	143	425.2	37.9	289	398	423	448	530
	Week 4	140	450.4	38.6	320	424	450	475	541
	Week 8	137	461.2	36.5	356	436	460	482	554
	Week 12	135	459.5	38.2	351	434	458	491	558
	Week 16	135	458.7	35.3	366	434	461	482	534
	Week 20	131	457.1	36.1	358	437	455	483	552
	Week 24	132	454.1	36.0	380	429	453	478	580
	End of Treatment	142	451.7	37.6	320	425	451	477	580
	Follow-up Week 4	116	436.8	37.8	346	410	436	465	532
	End of Follow-up	142	437.3	36.9	346	411	438	463	532
Leuprorelin	Screening	143	434.0	39.3	317	405	438	462	521
	Run-in	144	421.9	43.4	298	395	424	451	522
	Baseline	144	420.9	40.6	272	398	426	450	499
	Week 4	140	449.1	35.8	361	429	452	473	557
	Week 8	140	463.7	34.7	363	444	466	487	549
	Week 12	137	462.3	35.4	366	437	464	488	558
	Week 16	136	463.4	36.6	377	438	468	486	557
	Week 20	133	458.8	35.1	368	441	458	484	566
	Week 24	131	456.1	33.5	357	434	457	477	568
	End of Treatment	144	455.4	34.6	349	435	455	478	568

Table 14.3.1-19 Laboratory Tests

Parameter: Erythrocytes (10^4/uL)

Group	Time	N	Mean	SD	Min	Q1	Median	Q3	Max
	Follow-up Week 4	130	460.9	38.9	335	434	458	485	543
	End of Follow-up	144	460.4	37.7	335	434	459	485	543

Table 14.3.1-19 Laboratory Tests

Parameter: Leukocytes (/uL)

Group	Time	N	Mean	SD	Min	Q1	Median	Q3	Max
KLH-2109 200 mg	Screening	143	5830	1600	2800	4800	5600	6800	11400
	Run-in	143	5300	1740	2200	4300	5100	5900	15000
	Baseline	143	5330	1580	2500	4200	5100	6300	12300
	Week 4	140	4730	1160	2300	4000	4500	5500	8900
	Week 8	137	4940	1340	2500	4000	4600	5600	9800
	Week 12	135	4830	1290	2200	3800	4700	5700	8800
	Week 16	135	4990	1320	2200	4000	4900	5800	10600
	Week 20	131	5110	1430	2700	4000	4900	6000	10200
	Week 24	132	5110	1450	2600	4100	4800	6000	11200
	End of Treatment	142	5090	1450	2600	4100	4800	6000	11200
	Follow-up Week 4	116	5630	1360	3100	4700	5400	6500	9400
	End of Follow-up	142	5650	1360	2900	4700	5400	6500	9400
Leuprorelin	Screening	143	5820	1400	2300	4900	5700	6600	10900
	Run-in	144	5440	1380	2600	4500	5300	6300	9400
	Baseline	144	5200	1410	2600	4200	5000	6100	9800
	Week 4	140	4900	1210	2600	3900	4900	5600	8300
	Week 8	140	5150	1680	2600	4100	5000	6000	14800
	Week 12	137	4950	1220	2200	4100	4900	5800	8000
	Week 16	136	5110	1150	2900	4300	5000	5800	9700
	Week 20	133	5120	1390	2500	4200	5000	5800	12900
	Week 24	131	5150	1590	2800	4100	4900	5700	13500
	End of Treatment	144	5150	1560	2800	4100	4900	5800	13500

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Table 14.3.1-19 Laboratory Tests

Parameter: Leukocytes (/uL)

Group	Time	N	Mean	SD	Min	Q1	Median	Q3	Max
	Follow-up Week 4	130	5160	1260	2900	4300	5000	5900	9900
	End of Follow-up	144	5100	1250	2900	4300	4900	5800	9900

Table 14.3.1-19 Laboratory Tests

Parameter: Platelets (10^4/uL)

Group	Time	N	Mean	SD	Min	Q1	Median	Q3	Max
KLH-2109 200 mg	Screening	143	29.77	7.00	11.9	24.6	28.4	34.9	51.5
	Run-in	143	29.11	6.99	11.9	24.9	28.7	33.4	50.6
	Baseline	143	29.14	6.79	11.6	24.5	29.2	33.8	47.1
	Week 4	140	27.29	6.43	9.0	23.1	27.1	31.2	46.5
	Week 8	137	27.65	6.17	12.7	23.9	27.2	31.8	49.8
	Week 12	135	27.58	6.32	9.0	23.2	27.6	32.0	48.5
	Week 16	135	27.58	5.92	12.1	23.6	27.8	31.2	44.7
	Week 20	131	27.77	6.29	13.9	23.4	27.9	31.8	47.6
	Week 24	132	27.37	6.25	14.9	23.4	26.7	31.6	46.3
	End of Treatment	142	27.53	6.59	14.9	23.5	27.0	31.5	53.0
	Follow-up Week 4	116	27.74	6.19	13.3	24.0	27.2	31.9	52.2
	End of Follow-up	142	27.78	6.26	12.3	24.0	27.2	31.9	52.2
Leuprorelin	Screening	143	30.71	7.14	17.0	25.9	29.8	34.0	69.7
	Run-in	144	29.39	6.70	11.0	24.0	28.7	33.7	49.2
	Baseline	144	29.65	6.47	11.5	25.0	28.7	33.4	49.8
	Week 4	140	29.50	7.51	9.7	24.7	27.9	33.8	62.7
	Week 8	140	27.59	6.01	8.8	23.4	27.0	31.4	44.7
	Week 12	137	27.41	6.01	14.7	23.4	27.0	31.4	43.7
	Week 16	136	28.13	5.82	11.7	24.1	27.3	32.1	45.6
	Week 20	133	27.84	5.73	10.3	23.7	26.9	31.6	45.0
	Week 24	131	27.40	5.83	12.3	23.2	26.1	31.1	44.0
	End of Treatment	144	27.68	5.73	12.3	23.4	27.2	31.3	44.0

Table 14.3.1-19 Laboratory Tests

Parameter: Platelets (10^4/uL)

Group	Time	N	Mean	SD	Min	Q1	Median	Q3	Max
	Follow-up Week 4	130	27.67	5.99	11.0	23.6	27.3	31.4	44.0
	End of Follow-up	144	27.67	5.82	11.0	23.7	27.3	31.4	44.0

Table 14.3.1-19 Laboratory Tests

Parameter: Activated Partial Thromboplastin Time (sec)

Group	Time	N	Mean	SD	Min	Q1	Median	Q3	Max
KLH-2109 200 mg	Screening	143	30.52	3.03	23.4	28.4	30.6	32.2	42.0
	Run-in	143	30.42	3.15	22.1	28.2	30.3	31.9	43.4
	Baseline	143	30.40	3.17	23.1	28.1	30.1	32.2	44.9
	Week 4	140	31.73	3.51	24.4	29.2	31.6	33.2	46.6
	Week 8	137	32.34	3.81	24.2	29.7	32.0	34.5	46.6
	Week 12	136	32.71	3.62	24.5	30.1	32.5	35.3	44.5
	Week 16	135	32.94	4.06	23.0	30.4	32.6	35.4	46.0
	Week 20	131	33.22	3.75	25.8	30.1	33.3	35.6	44.3
	Week 24	132	33.78	3.91	26.4	31.0	33.8	36.1	48.5
	End of Treatment	142	33.50	4.00	26.0	30.8	33.4	35.8	48.5
	Follow-up Week 4	116	33.00	3.84	25.4	30.1	32.6	35.4	46.8
	End of Follow-up	142	32.80	3.83	25.4	29.8	32.4	35.2	46.8
Leuprorelin	Screening	144	30.16	2.67	24.2	28.3	30.0	32.0	37.7
	Run-in	144	30.02	2.79	22.6	28.2	29.7	32.1	36.4
	Baseline	144	30.33	2.73	24.4	28.3	30.4	32.2	38.1
	Week 4	140	31.51	3.07	25.1	29.1	31.3	33.5	40.1
	Week 8	140	32.05	3.09	23.9	29.7	32.4	34.1	40.9
	Week 12	137	32.78	3.16	26.9	30.7	32.2	34.6	45.2
	Week 16	136	32.61	3.48	23.9	30.5	32.4	34.8	41.2
	Week 20	133	33.02	3.38	27.0	30.6	32.8	35.0	41.6
	Week 24	130	33.66	3.40	24.2	31.5	33.3	35.8	43.9
	End of Treatment	144	33.58	3.38	24.2	31.2	33.3	35.8	43.9

Table 14.3.1-19 Laboratory Tests

Parameter: Activated Partial Thromboplastin Time (sec)

Group	Time	N	Mean	SD	Min	Q1	Median	Q3	Max
	Follow-up Week 4	130	33.78	3.59	25.9	31.8	33.5	35.3	50.5
	End of Follow-up	144	33.72	3.54	25.9	31.6	33.5	35.4	50.5

Table 14.3.1-19 Laboratory Tests

Parameter: Prothrombin Time (sec)

Group	Time	N	Mean	SD	Min	Q1	Median	Q3	Max
KLH-2109 200 mg	Screening	143	10.93	0.67	9.4	10.5	10.9	11.3	13.5
	Run-in	143	10.83	0.67	9.5	10.4	10.8	11.2	13.3
	Baseline	143	10.82	0.68	9.3	10.4	10.7	11.3	14.0
	Week 4	140	10.68	0.67	9.3	10.2	10.7	11.0	13.6
	Week 8	137	10.63	0.65	9.6	10.1	10.5	11.0	12.9
	Week 12	136	10.73	0.67	9.3	10.3	10.6	11.2	13.0
	Week 16	135	10.81	0.68	9.5	10.4	10.8	11.2	14.1
	Week 20	131	10.78	0.65	8.9	10.4	10.7	11.2	12.8
	Week 24	132	10.90	0.68	9.5	10.4	10.9	11.3	13.0
	End of Treatment	142	10.88	0.69	9.4	10.4	10.9	11.3	13.0
	Follow-up Week 4	116	11.21	0.71	9.8	10.8	11.2	11.6	14.1
	End of Follow-up	142	11.21	0.75	9.7	10.8	11.2	11.6	14.1
Leuprorelin	Screening	144	10.80	0.69	8.9	10.4	10.9	11.2	12.7
	Run-in	144	10.76	0.76	8.8	10.3	10.8	11.2	12.9
	Baseline	144	10.72	0.70	9.1	10.3	10.7	11.1	12.6
	Week 4	140	10.64	0.72	9.2	10.1	10.7	11.0	13.2
	Week 8	140	10.62	0.67	8.8	10.3	10.6	11.0	12.5
	Week 12	137	10.74	0.65	9.1	10.4	10.8	11.1	12.4
	Week 16	136	10.86	0.71	8.9	10.4	10.9	11.3	12.6
	Week 20	133	10.85	0.64	9.0	10.4	10.8	11.3	12.3
	Week 24	131	10.92	0.72	7.7	10.5	10.9	11.4	12.7
	End of Treatment	144	10.91	0.71	7.7	10.5	10.9	11.3	12.7

Table 14.3.1-19 Laboratory Tests

Parameter: Prothrombin Time (sec)

Group	Time	N	Mean	SD	Min	Q1	Median	Q3	Max
	Follow-up Week 4	130	10.93	0.61	9.6	10.6	10.9	11.3	12.4
	End of Follow-up	144	10.93	0.61	9.6	10.6	10.9	11.3	12.4

Table 14.3.1-19 Laboratory Tests

Parameter: Prothrombin Intl. Normalized Ratio

Group	Time	N	Mean	SD	Min	Q1	Median	Q3	Max
KLH-2109 200 mg	Screening	143	0.980	0.060	0.85	0.94	0.97	1.01	1.21
	Run-in	143	0.974	0.059	0.86	0.93	0.97	1.01	1.19
	Baseline	143	0.976	0.059	0.84	0.94	0.97	1.02	1.25
	Week 4	140	0.964	0.058	0.84	0.92	0.97	0.99	1.22
	Week 8	137	0.958	0.056	0.87	0.91	0.95	0.99	1.16
	Week 12	136	0.963	0.059	0.84	0.92	0.96	1.00	1.16
	Week 16	135	0.967	0.058	0.84	0.93	0.96	1.00	1.26
	Week 20	131	0.961	0.054	0.81	0.92	0.96	0.99	1.15
	Week 24	132	0.968	0.054	0.86	0.93	0.96	1.00	1.13
	End of Treatment	142	0.967	0.055	0.85	0.93	0.96	1.00	1.13
	Follow-up Week 4	116	0.991	0.059	0.89	0.96	0.98	1.03	1.22
	End of Follow-up	142	0.992	0.062	0.85	0.95	0.98	1.03	1.22
Leuprorelin	Screening	144	0.969	0.058	0.81	0.93	0.97	1.00	1.14
	Run-in	144	0.968	0.065	0.80	0.93	0.97	1.01	1.16
	Baseline	144	0.967	0.060	0.83	0.93	0.97	1.00	1.13
	Week 4	140	0.960	0.062	0.84	0.91	0.97	0.99	1.18
	Week 8	140	0.958	0.059	0.80	0.92	0.95	0.99	1.12
	Week 12	137	0.965	0.056	0.82	0.93	0.97	1.00	1.11
	Week 16	136	0.971	0.061	0.81	0.93	0.97	1.01	1.13
	Week 20	133	0.966	0.055	0.82	0.93	0.97	0.99	1.10
	Week 24	131	0.969	0.063	0.69	0.92	0.97	1.01	1.10
	End of Treatment	144	0.969	0.061	0.69	0.92	0.97	1.01	1.10

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Table 14.3.1-19 Laboratory Tests

Parameter: Prothrombin Intl. Normalized Ratio

Group	Time	N	Mean	SD	Min	Q1	Median	Q3	Max
	Follow-up Week 4	130	0.966	0.050	0.85	0.93	0.97	1.00	1.11
	End of Follow-up	144	0.967	0.050	0.85	0.93	0.97	1.01	1.11

Table 14.3.1-19 Laboratory Tests

Parameter: Sodium (mEq/L)

Group	Time	N	Mean	SD	Min	Q1	Median	Q3	Max
KLH-2109 200 mg	Screening	143	139.4	1.6	136	138	139	141	144
	Run-in	143	140.0	1.5	135	139	140	141	145
	Baseline	143	139.9	1.4	135	139	140	141	144
	Week 4	140	140.6	1.5	137	140	141	142	145
	Week 8	137	140.9	1.5	136	140	141	142	144
	Week 12	136	141.0	1.3	137	140	141	142	145
	Week 16	135	140.9	1.4	137	140	141	142	144
	Week 20	131	141.2	1.5	137	140	141	142	144
	Week 24	132	141.0	1.5	137	140	141	142	145
	End of Treatment	142	141.0	1.5	137	140	141	142	145
	Follow-up Week 4	116	139.7	1.8	135	138	140	141	144
	End of Follow-up	142	139.7	1.8	135	138	140	141	144
Leuprorelin	Screening	144	139.5	1.5	134	138	140	141	143
	Run-in	144	140.1	1.4	137	139	140	141	143
	Baseline	144	139.9	1.5	135	139	140	141	145
	Week 4	140	140.6	1.5	137	140	141	142	145
	Week 8	140	140.8	1.4	138	140	141	142	143
	Week 12	137	141.2	1.4	138	140	141	142	145
	Week 16	136	141.2	1.6	137	140	141	142	145
	Week 20	133	141.3	1.5	137	140	141	142	145
	Week 24	131	141.5	1.5	138	141	142	142	146
	End of Treatment	144	141.4	1.5	138	140	141	142	146

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Table 14.3.1-19 Laboratory Tests

Parameter: Sodium (mEq/L)

Group	Time	N	Mean	SD	Min	Q1	Median	Q3	Max
	Follow-up Week 4	130	141.0	1.5	138	140	141	142	144
	End of Follow-up	144	141.0	1.4	138	140	141	142	144

Table 14.3.1-19 Laboratory Tests

Parameter: Potassium (mEq/L)

Group	Time	N	Mean	SD	Min	Q1	Median	Q3	Max
KLH-2109 200 mg	Screening	143	4.06	0.24	3.5	3.9	4.1	4.2	4.7
	Run-in	143	4.08	0.31	3.3	3.9	4.1	4.3	5.0
	Baseline	143	4.10	0.29	3.3	3.9	4.1	4.3	4.8
	Week 4	140	4.09	0.25	3.6	3.9	4.1	4.3	4.9
	Week 8	137	4.11	0.28	3.5	3.9	4.1	4.3	5.1
	Week 12	136	4.07	0.27	3.4	3.9	4.1	4.2	5.0
	Week 16	135	4.10	0.26	3.5	3.9	4.1	4.3	5.1
	Week 20	131	4.14	0.31	3.6	3.9	4.1	4.3	5.3
	Week 24	132	4.05	0.26	3.4	3.9	4.0	4.2	4.7
	End of Treatment	142	4.06	0.26	3.4	3.9	4.0	4.3	4.7
	Follow-up Week 4	116	4.08	0.25	3.5	3.9	4.1	4.2	5.0
	End of Follow-up	142	4.07	0.27	3.4	3.9	4.1	4.2	5.0
Leuprorelin	Screening	144	4.07	0.26	3.5	3.9	4.1	4.2	5.0
	Run-in	144	4.04	0.28	3.3	3.8	4.1	4.2	4.9
	Baseline	144	4.05	0.26	3.3	3.9	4.1	4.2	4.8
	Week 4	140	4.11	0.27	3.5	3.9	4.1	4.3	5.1
	Week 8	140	4.11	0.31	3.4	3.9	4.1	4.3	5.4
	Week 12	137	4.05	0.28	3.6	3.9	4.0	4.2	5.1
	Week 16	136	4.11	0.28	3.5	3.9	4.1	4.3	4.9
	Week 20	133	4.06	0.25	3.5	3.9	4.1	4.2	4.9
	Week 24	131	4.03	0.29	3.2	3.8	4.0	4.2	5.1
	End of Treatment	144	4.03	0.29	3.2	3.8	4.0	4.2	5.1

Table 14.3.1-19 Laboratory Tests

Parameter: Potassium (mEq/L)

Group	Time	N	Mean	SD	Min	Q1	Median	Q3	Max
	Follow-up Week 4	130	4.07	0.26	3.5	3.9	4.0	4.2	5.0
	End of Follow-up	144	4.08	0.26	3.5	3.9	4.1	4.3	5.0

Table 14.3.1-19 Laboratory Tests

Parameter: Calcium (mg/dL)

Group	Time	N	Mean	SD	Min	Q1	Median	Q3	Max
KLH-2109 200 mg	Screening	143	9.08	0.25	8.3	8.9	9.1	9.2	10.0
	Run-in	143	9.00	0.31	8.1	8.8	9.0	9.2	9.8
	Baseline	143	9.02	0.32	8.1	8.8	9.0	9.2	10.0
	Week 4	140	9.35	0.28	8.7	9.2	9.4	9.5	10.1
	Week 8	137	9.48	0.28	8.8	9.3	9.4	9.6	10.4
	Week 12	136	9.52	0.29	9.0	9.3	9.5	9.7	10.3
	Week 16	135	9.55	0.30	8.7	9.4	9.5	9.7	10.4
	Week 20	131	9.55	0.32	8.7	9.4	9.6	9.8	10.4
	Week 24	132	9.55	0.29	8.9	9.3	9.5	9.8	10.4
	End of Treatment	142	9.54	0.29	8.9	9.3	9.5	9.8	10.4
	Follow-up Week 4	116	9.12	0.24	8.5	8.9	9.1	9.3	9.6
	End of Follow-up	142	9.12	0.25	8.5	8.9	9.1	9.3	9.6
Leuprorelin	Screening	144	9.10	0.29	8.3	8.9	9.1	9.3	9.7
	Run-in	144	9.01	0.31	8.4	8.8	9.0	9.2	9.9
	Baseline	144	9.00	0.31	8.2	8.8	9.0	9.2	9.8
	Week 4	140	9.27	0.27	8.6	9.1	9.2	9.4	10.0
	Week 8	140	9.46	0.27	8.8	9.3	9.5	9.7	10.0
	Week 12	137	9.46	0.29	8.7	9.3	9.4	9.6	10.4
	Week 16	136	9.50	0.28	8.8	9.3	9.5	9.7	10.2
	Week 20	133	9.51	0.29	8.8	9.3	9.5	9.7	10.3
	Week 24	131	9.47	0.30	8.9	9.3	9.5	9.7	10.3
	End of Treatment	144	9.46	0.31	8.4	9.3	9.5	9.7	10.3

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Table 14.3.1-19 Laboratory Tests

Parameter: Calcium (mg/dL)

Group	Time	N	Mean	SD	Min	Q1	Median	Q3	Max
	Follow-up Week 4	130	9.45	0.34	8.5	9.2	9.4	9.7	10.4
	End of Follow-up	144	9.45	0.34	8.5	9.2	9.4	9.7	10.4

Table 14.3.1-19 Laboratory Tests

Parameter: Phosphate (mg/dL)

Group	Time	N	Mean	SD	Min	Q1	Median	Q3	Max
KLH-2109 200 mg	Screening	143	3.48	0.53	1.4	3.2	3.5	3.8	4.6
	Run-in	143	3.56	0.51	1.4	3.3	3.6	3.9	4.7
	Baseline	143	3.59	0.44	2.2	3.3	3.6	3.9	4.7
	Week 4	140	3.86	0.38	3.0	3.6	3.9	4.1	5.0
	Week 8	137	4.07	0.44	2.6	3.8	4.1	4.3	5.6
	Week 12	136	4.13	0.42	3.2	3.8	4.1	4.4	5.2
	Week 16	135	4.12	0.41	2.7	3.9	4.1	4.5	5.1
	Week 20	131	4.17	0.50	2.4	3.8	4.2	4.5	5.5
	Week 24	132	4.13	0.45	3.1	3.8	4.1	4.4	5.1
	End of Treatment	142	4.11	0.46	3.1	3.7	4.1	4.4	5.1
	Follow-up Week 4	116	3.74	0.41	2.6	3.5	3.8	4.0	4.8
	End of Follow-up	142	3.75	0.43	2.1	3.5	3.8	4.0	4.8
Leuprorelin	Screening	144	3.49	0.53	1.1	3.2	3.6	3.9	4.5
	Run-in	144	3.56	0.51	1.6	3.3	3.6	3.9	5.0
	Baseline	144	3.56	0.43	2.3	3.3	3.5	3.9	4.6
	Week 4	140	3.88	0.47	2.6	3.6	3.9	4.2	5.3
	Week 8	140	4.00	0.47	2.7	3.7	4.0	4.3	5.2
	Week 12	137	4.18	0.46	3.1	3.9	4.2	4.5	5.3
	Week 16	136	4.20	0.48	2.3	3.9	4.3	4.5	5.2
	Week 20	133	4.20	0.50	2.6	3.9	4.2	4.6	5.3
	Week 24	131	4.23	0.48	2.6	3.9	4.3	4.6	5.1
	End of Treatment	144	4.22	0.48	2.6	3.9	4.3	4.6	5.3

Table 14.3.1-19 Laboratory Tests

Parameter: Phosphate (mg/dL)

Group	Time	N	Mean	SD	Min	Q1	Median	Q3	Max
	Follow-up Week 4	130	4.06	0.51	2.7	3.7	4.1	4.4	5.3
	End of Follow-up	144	4.07	0.52	2.7	3.7	4.1	4.4	5.3

Table 14.3.1-19 Laboratory Tests

Parameter: Creatinine (mg/dL)

Group	Time	N	Mean	SD	Min	Q1	Median	Q3	Max
KLH-2109 200 mg	Screening	143	0.603	0.079	0.43	0.54	0.60	0.66	0.89
	Run-in	143	0.618	0.078	0.44	0.57	0.62	0.66	0.98
	Baseline	143	0.612	0.079	0.45	0.56	0.61	0.66	0.93
	Week 4	140	0.668	0.088	0.49	0.60	0.67	0.72	1.05
	Week 8	137	0.671	0.091	0.44	0.60	0.67	0.72	1.04
	Week 12	136	0.660	0.091	0.43	0.60	0.66	0.71	0.99
	Week 16	135	0.657	0.086	0.42	0.60	0.66	0.72	0.94
	Week 20	131	0.658	0.096	0.44	0.60	0.66	0.72	0.99
	Week 24	132	0.660	0.087	0.49	0.60	0.66	0.72	0.88
	End of Treatment	142	0.659	0.088	0.49	0.59	0.66	0.72	0.88
	Follow-up Week 4	116	0.608	0.087	0.43	0.56	0.60	0.66	0.91
	End of Follow-up	142	0.610	0.086	0.43	0.56	0.60	0.66	0.91
Leuprorelin	Screening	144	0.606	0.088	0.47	0.54	0.60	0.65	0.91
	Run-in	144	0.619	0.088	0.40	0.57	0.61	0.67	0.87
	Baseline	144	0.609	0.090	0.42	0.55	0.61	0.66	0.91
	Week 4	140	0.618	0.095	0.41	0.56	0.62	0.66	0.94
	Week 8	140	0.623	0.092	0.42	0.56	0.61	0.67	0.88
	Week 12	137	0.627	0.092	0.43	0.57	0.61	0.67	0.92
	Week 16	136	0.624	0.092	0.43	0.56	0.61	0.67	0.95
	Week 20	133	0.616	0.085	0.41	0.56	0.62	0.66	0.92
	Week 24	131	0.619	0.090	0.45	0.55	0.61	0.67	0.94
	End of Treatment	144	0.617	0.092	0.43	0.55	0.61	0.67	0.94

Table 14.3.1-19 Laboratory Tests

Parameter: Creatinine (mg/dL)

Group	Time	N	Mean	SD	Min	Q1	Median	Q3	Max
	Follow-up Week 4	130	0.624	0.093	0.42	0.57	0.61	0.67	0.93
	End of Follow-up	144	0.621	0.091	0.42	0.57	0.61	0.66	0.93

Table 14.3.1-19 Laboratory Tests

Parameter: Bilirubin (mg/dL)

Group	Time	N	Mean	SD	Min	Q1	Median	Q3	Max
KLH-2109 200 mg	Screening	143	0.64	0.25	0.2	0.5	0.6	0.8	1.7
	Run-in	143	0.62	0.25	0.3	0.4	0.6	0.8	1.7
	Baseline	143	0.63	0.26	0.3	0.4	0.6	0.8	1.7
	Week 4	140	0.67	0.30	0.2	0.5	0.6	0.8	1.7
	Week 8	137	0.67	0.25	0.3	0.5	0.6	0.8	1.5
	Week 12	136	0.70	0.26	0.3	0.5	0.7	0.8	1.6
	Week 16	135	0.71	0.27	0.3	0.5	0.7	0.9	1.7
	Week 20	131	0.71	0.29	0.3	0.5	0.7	0.8	2.2
	Week 24	132	0.73	0.27	0.3	0.5	0.7	0.8	1.8
	End of Treatment	142	0.73	0.27	0.3	0.5	0.7	0.8	1.8
	Follow-up Week 4	116	0.75	0.33	0.3	0.5	0.7	0.9	2.3
	End of Follow-up	142	0.74	0.31	0.3	0.6	0.7	0.9	2.3
Leuprorelin	Screening	144	0.65	0.26	0.3	0.5	0.6	0.8	1.8
	Run-in	144	0.58	0.20	0.2	0.4	0.6	0.7	1.3
	Baseline	144	0.58	0.23	0.2	0.4	0.6	0.7	1.8
	Week 4	140	0.64	0.24	0.2	0.5	0.6	0.8	1.8
	Week 8	140	0.70	0.29	0.3	0.5	0.6	0.8	2.2
	Week 12	137	0.70	0.29	0.3	0.5	0.6	0.9	2.1
	Week 16	136	0.75	0.28	0.3	0.6	0.7	0.9	1.9
	Week 20	133	0.78	0.34	0.3	0.6	0.7	0.9	2.7
	Week 24	131	0.73	0.25	0.3	0.6	0.7	0.9	1.5
	End of Treatment	144	0.72	0.25	0.3	0.5	0.7	0.9	1.5

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Table 14.3.1-19 Laboratory Tests

Parameter: Bilirubin (mg/dL)

Group	Time	N	Mean	SD	Min	Q1	Median	Q3	Max
	Follow-up Week 4	130	0.75	0.27	0.3	0.5	0.7	0.9	1.7
	End of Follow-up	144	0.74	0.26	0.3	0.5	0.7	0.9	1.7

Table 14.3.1-19 Laboratory Tests

Parameter: Protein (g/dL)

Group	Time	N	Mean	SD	Min	Q1	Median	Q3	Max
KLH-2109 200 mg	Screening	143	6.97	0.35	6.0	6.7	7.0	7.2	7.8
	Run-in	143	6.86	0.39	5.7	6.6	6.8	7.1	8.1
	Baseline	143	6.89	0.39	5.9	6.7	6.9	7.1	8.0
	Week 4	140	7.21	0.41	6.2	7.0	7.2	7.5	8.2
	Week 8	137	7.28	0.36	6.5	7.0	7.3	7.5	8.3
	Week 12	136	7.25	0.40	6.2	7.0	7.2	7.5	8.7
	Week 16	135	7.29	0.38	6.2	7.1	7.3	7.5	8.5
	Week 20	131	7.27	0.36	6.3	7.1	7.3	7.5	8.1
	Week 24	132	7.25	0.40	6.2	7.0	7.2	7.5	8.6
	End of Treatment	142	7.24	0.40	6.2	7.0	7.2	7.5	8.6
	Follow-up Week 4	116	6.94	0.36	6.0	6.7	6.9	7.2	7.9
	End of Follow-up	142	6.95	0.37	6.0	6.7	6.9	7.2	8.4
Leuprorelin	Screening	144	6.93	0.35	5.7	6.7	6.9	7.1	8.1
	Run-in	144	6.82	0.39	5.8	6.6	6.8	7.1	7.8
	Baseline	144	6.79	0.38	5.5	6.5	6.8	7.0	7.9
	Week 4	140	7.09	0.35	6.3	6.8	7.1	7.3	8.2
	Week 8	140	7.23	0.35	6.3	7.0	7.2	7.5	8.8
	Week 12	137	7.14	0.38	6.3	6.8	7.1	7.3	8.4
	Week 16	136	7.21	0.36	6.3	7.0	7.2	7.4	8.3
	Week 20	133	7.22	0.35	6.4	7.0	7.2	7.4	8.4
	Week 24	131	7.14	0.41	6.2	6.9	7.1	7.4	8.2
	End of Treatment	144	7.14	0.42	6.2	6.9	7.1	7.4	8.2

Table 14.3.1-19 Laboratory Tests

Parameter: Protein (g/dL)

Group	Time	N	Mean	SD	Min	Q1	Median	Q3	Max
	Follow-up Week 4	130	7.19	0.44	6.1	6.9	7.2	7.5	8.8
	End of Follow-up	144	7.16	0.45	6.0	6.9	7.1	7.4	8.8

Table 14.3.1-19 Laboratory Tests

Parameter: Albumin (g/dL)

Group	Time	N	Mean	SD	Min	Q1	Median	Q3	Max
KLH-2109 200 mg	Screening	143	4.20	0.22	3.7	4.1	4.2	4.4	4.7
	Run-in	143	4.12	0.25	3.4	4.0	4.1	4.3	4.9
	Baseline	143	4.13	0.23	3.5	4.0	4.1	4.3	4.8
	Week 4	140	4.32	0.24	3.8	4.1	4.3	4.5	5.0
	Week 8	137	4.35	0.23	3.8	4.2	4.4	4.5	5.2
	Week 12	136	4.33	0.25	3.7	4.2	4.3	4.5	5.1
	Week 16	135	4.35	0.23	3.7	4.2	4.4	4.5	5.1
	Week 20	131	4.34	0.25	3.8	4.2	4.4	4.5	5.0
	Week 24	132	4.34	0.25	3.8	4.2	4.4	4.5	5.0
	End of Treatment	142	4.33	0.25	3.8	4.2	4.3	4.5	5.0
	Follow-up Week 4	116	4.15	0.24	3.6	4.0	4.1	4.3	4.8
	End of Follow-up	142	4.15	0.24	3.6	4.0	4.1	4.3	4.8
Leuprorelin	Screening	144	4.19	0.23	3.6	4.0	4.2	4.4	4.8
	Run-in	144	4.11	0.22	3.5	4.0	4.1	4.2	4.9
	Baseline	144	4.10	0.24	3.5	3.9	4.1	4.3	4.9
	Week 4	140	4.29	0.21	3.6	4.1	4.3	4.4	4.8
	Week 8	140	4.36	0.24	3.8	4.2	4.4	4.5	5.0
	Week 12	137	4.29	0.23	3.7	4.1	4.3	4.4	5.0
	Week 16	136	4.34	0.24	3.8	4.2	4.3	4.5	5.1
	Week 20	133	4.35	0.22	3.8	4.2	4.3	4.5	4.9
	Week 24	131	4.31	0.23	3.9	4.1	4.3	4.5	4.8
	End of Treatment	144	4.30	0.23	3.9	4.1	4.3	4.5	4.8

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Table 14.3.1-19 Laboratory Tests

Parameter: Albumin (g/dL)

Group	Time	N	Mean	SD	Min	Q1	Median	Q3	Max
	Follow-up Week 4	130	4.31	0.26	3.6	4.1	4.3	4.5	4.9
	End of Follow-up	144	4.31	0.26	3.6	4.1	4.3	4.5	4.9

Table 14.3.1-19 Laboratory Tests

Parameter: Aspartate Aminotransferase (U/L)

Group	Time	N	Mean	SD	Min	Q1	Median	Q3	Max
KLH-2109 200 mg	Screening	143	16.9	4.7	9	13	16	19	34
	Run-in	143	16.7	4.7	8	13	16	19	33
	Baseline	143	16.5	4.7	7	13	16	18	35
	Week 4	140	20.9	6.6	9	16	19	24	46
	Week 8	137	24.0	12.1	11	17	21	27	112
	Week 12	136	22.9	8.4	11	17	21	26	58
	Week 16	135	24.0	14.1	10	17	21	26	150
	Week 20	131	23.3	10.7	10	17	21	26	76
	Week 24	132	23.9	13.4	11	17	20	25	114
	End of Treatment	142	23.8	13.4	11	17	20	25	114
	Follow-up Week 4	116	19.0	8.0	9	14	18	21	68
	End of Follow-up	142	18.7	7.4	9	14	17	21	68
Leuprorelin	Screening	144	17.2	4.6	9	14	17	19	39
	Run-in	144	17.0	5.1	10	14	16	19	45
	Baseline	144	17.0	6.4	7	14	16	19	70
	Week 4	140	18.9	6.2	10	15	18	21	53
	Week 8	140	19.6	6.9	10	16	18	21	69
	Week 12	137	20.0	6.6	11	16	19	22	58
	Week 16	136	20.3	7.2	10	16	19	22	67
	Week 20	133	21.0	9.1	11	17	19	23	84
	Week 24	131	20.6	7.4	10	17	19	22	51
	End of Treatment	144	20.5	7.4	10	17	19	22	51

Table 14.3.1-19 Laboratory Tests

Parameter: Aspartate Aminotransferase (U/L)

Group	Time	N	Mean	SD	Min	Q1	Median	Q3	Max
	Follow-up Week 4	130	20.8	7.8	10	16	19	23	62
	End of Follow-up	144	20.7	7.6	10	16	19	23	62

Table 14.3.1-19 Laboratory Tests

Parameter: Alanine Aminotransferase (U/L)

Group	Time	N	Mean	SD	Min	Q1	Median	Q3	Max
KLH-2109 200 mg	Screening	143	14.8	7.7	5	10	12	17	43
	Run-in	143	13.8	8.3	5	9	11	15	64
	Baseline	143	13.8	6.9	5	10	12	15	40
	Week 4	140	21.9	15.4	5	13	17	26	112
	Week 8	137	27.6	22.5	8	14	19	35	144
	Week 12	136	26.1	17.9	7	14	20	32	92
	Week 16	135	27.0	19.0	6	14	21	33	107
	Week 20	131	26.2	18.6	5	14	20	33	104
	Week 24	132	27.5	24.1	6	15	20	30	173
	End of Treatment	142	27.4	24.1	6	15	20	29	173
	Follow-up Week 4	116	17.7	13.4	5	10	14	19	98
	End of Follow-up	142	17.3	12.6	5	10	14	19	98
Leuprorelin	Screening	144	15.5	10.1	2	10	13	17	78
	Run-in	144	14.3	8.9	1	9	12	17	63
	Baseline	144	14.3	9.3	1	9	13	17	70
	Week 4	140	18.1	11.8	2	11	16	21	90
	Week 8	140	18.7	14.0	1	12	16	21	113
	Week 12	137	19.9	14.2	2	12	16	23	105
	Week 16	136	20.5	15.7	1	12	16	23	132
	Week 20	133	21.7	21.8	1	12	16	23	178
	Week 24	131	21.2	16.7	1	12	16	24	108
	End of Treatment	144	20.7	16.4	1	12	16	23	108

Table 14.3.1-19 Laboratory Tests

Parameter: Alanine Aminotransferase (U/L)

Group	Time	N	Mean	SD	Min	Q1	Median	Q3	Max
	Follow-up Week 4	130	21.9	19.3	1	12	17	22	130
	End of Follow-up	144	21.4	18.7	1	12	16	22	130

Table 14.3.1-19 Laboratory Tests

Parameter: Gamma Glutamyl Transferase (U/L)

Group	Time	N	Mean	SD	Min	Q1	Median	Q3	Max
KLH-2109 200 mg	Screening	143	20.1	16.3	7	11	14	22	100
	Run-in	143	20.4	20.5	7	11	14	20	146
	Baseline	143	19.8	15.8	7	11	14	22	105
	Week 4	140	25.7	23.8	7	13	17	27	132
	Week 8	137	27.8	28.0	7	13	17	27	195
	Week 12	136	27.6	26.1	8	13	18	28	151
	Week 16	135	29.4	34.3	8	14	19	29	309
	Week 20	131	29.5	31.0	8	14	19	30	201
	Week 24	132	28.4	24.7	8	14	20	30	134
	End of Treatment	142	27.6	24.0	8	14	19	29	134
	Follow-up Week 4	116	23.9	19.7	7	12	16	26	114
	End of Follow-up	142	22.6	18.3	7	12	16	24	114
Leuprorelin	Screening	144	19.0	22.2	7	11	14	20	259
	Run-in	144	18.8	22.8	7	11	15	20	267
	Baseline	144	19.0	20.9	7	11	14	20	218
	Week 4	140	21.6	21.3	7	12	15	22	214
	Week 8	140	23.0	24.6	8	13	16	24	246
	Week 12	137	24.3	27.6	7	13	17	24	277
	Week 16	136	25.7	31.2	8	13	17	26	311
	Week 20	133	27.6	39.7	8	13	17	28	418
	Week 24	131	27.2	33.8	8	13	17	28	330
	End of Treatment	144	26.2	32.6	8	13	17	27	330

Table 14.3.1-19 Laboratory Tests

Parameter: Gamma Glutamyl Transferase (U/L)

Group	Time	N	Mean	SD	Min	Q1	Median	Q3	Max
	Follow-up Week 4	130	28.5	40.4	7	13	16	28	403
	End of Follow-up	144	27.5	38.6	7	13	16	26	403

Table 14.3.1-19 Laboratory Tests

Parameter: Alkaline Phosphatase (U/L)

Group	Time	N	Mean	SD	Min	Q1	Median	Q3	Max
KLH-2109 200 mg	Screening	143	57.1	17.6	24	45	56	65	179
	Run-in	143	57.2	17.2	28	46	56	63	166
	Baseline	143	56.5	15.9	25	45	54	64	140
	Week 4	140	59.4	16.1	30	48	57	67	114
	Week 8	137	61.6	15.8	31	51	59	70	134
	Week 12	136	62.6	15.4	33	50	60	71	110
	Week 16	135	66.1	18.3	32	54	62	74	163
	Week 20	131	68.6	16.4	34	56	66	79	127
	Week 24	132	69.6	17.1	37	56	67	80	118
	End of Treatment	142	69.0	17.0	37	56	65	80	118
	Follow-up Week 4	116	70.6	17.6	39	55	70	81	119
	End of Follow-up	142	70.5	18.3	36	55	69	81	128
Leuprorelin	Screening	144	55.7	13.8	24	46	57	65	95
	Run-in	144	55.1	13.9	26	44	56	64	90
	Baseline	144	55.2	14.4	25	45	55	65	108
	Week 4	140	58.7	15.1	27	47	59	70	107
	Week 8	140	60.8	15.9	29	48	60	74	97
	Week 12	137	63.3	15.5	30	51	62	75	101
	Week 16	136	66.2	16.6	30	53	65	79	102
	Week 20	133	68.8	17.6	28	56	67	82	117
	Week 24	131	70.9	16.7	28	58	71	83	111
	End of Treatment	144	70.0	17.0	28	57	69	83	111

Table 14.3.1-19 Laboratory Tests

Parameter: Alkaline Phosphatase (U/L)

Group	Time	N	Mean	SD	Min	Q1	Median	Q3	Max
	Follow-up Week 4	130	73.2	18.3	33	59	73	85	115
	End of Follow-up	144	72.4	18.1	33	58	73	85	115

Table 14.3.1-19 Laboratory Tests

Parameter: Creatine Kinase (U/L)

Group	Time	N	Mean	SD	Min	Q1	Median	Q3	Max
KLH-2109 200 mg	Screening	143	70.4	31.9	24	49	62	81	197
	Run-in	143	79.7	52.9	31	58	69	88	550
	Baseline	143	70.6	25.5	29	54	65	84	181
	Week 4	140	75.5	26.2	20	56	69	91	143
	Week 8	137	79.4	38.2	24	56	72	92	360
	Week 12	136	75.3	29.4	20	57	69	90	250
	Week 16	135	162.7	1023.5	25	55	71	88	11963
	Week 20	131	76.3	27.8	30	56	69	92	201
	Week 24	132	78.4	30.4	28	58	75	91	201
	End of Treatment	142	87.8	123.8	28	58	74	90	1510
	Follow-up Week 4	116	72.2	32.6	28	50	63	87	198
	End of Follow-up	142	72.8	35.0	28	51	64	87	275
Leuprorelin	Screening	144	77.3	45.2	25	55	69	87	481
	Run-in	144	81.5	42.7	21	56	74	94	379
	Baseline	144	93.6	129.5	27	58	72	96	1320
	Week 4	140	88.0	88.3	25	58	76	95	1023
	Week 8	140	94.7	77.1	30	63	77	104	797
	Week 12	137	85.8	31.8	33	65	81	102	222
	Week 16	136	90.1	61.6	34	60	78	104	581
	Week 20	133	89.2	44.1	32	63	81	103	352
	Week 24	131	81.8	29.2	36	58	76	101	177
	End of Treatment	144	81.8	31.6	34	58	75	100	210

Table 14.3.1-19 Laboratory Tests

Parameter: Creatine Kinase (U/L)

Group	Time	N	Mean	SD	Min	Q1	Median	Q3	Max
	Follow-up Week 4	130	91.8	50.8	34	59	80	105	340
	End of Follow-up	144	91.5	54.5	34	60	77	101	373

Table 14.3.1-19 Laboratory Tests

Parameter: Urate (mg/dL)

Group	Time	N	Mean	SD	Min	Q1	Median	Q3	Max
KLH-2109 200 mg	Screening	143	4.22	0.93	1.8	3.7	4.2	4.7	7.5
	Run-in	143	4.26	0.98	1.8	3.7	4.1	4.9	7.2
	Baseline	143	4.23	0.87	2.3	3.7	4.2	4.7	7.1
	Week 4	140	4.34	0.92	2.1	3.7	4.2	4.9	6.6
	Week 8	137	4.44	0.99	1.7	3.8	4.4	5.1	7.4
	Week 12	136	4.66	1.03	2.5	4.0	4.7	5.2	7.9
	Week 16	135	4.66	0.95	2.5	4.0	4.6	5.3	7.4
	Week 20	131	4.77	0.94	1.9	4.1	4.8	5.4	7.3
	Week 24	132	4.78	1.00	2.0	4.2	4.7	5.4	7.1
	End of Treatment	142	4.71	1.03	2.0	4.0	4.7	5.4	7.1
	Follow-up Week 4	116	4.57	0.97	1.7	4.0	4.5	5.4	6.6
	End of Follow-up	142	4.56	0.97	1.7	4.0	4.5	5.3	6.7
Leuprorelin	Screening	144	4.22	1.03	1.9	3.5	4.1	4.8	7.5
	Run-in	144	4.27	1.02	2.1	3.6	4.2	5.0	6.9
	Baseline	144	4.36	1.00	2.3	3.6	4.2	5.0	7.2
	Week 4	140	4.50	0.99	2.3	3.9	4.4	5.1	7.2
	Week 8	140	4.57	1.06	2.1	3.8	4.5	5.2	7.5
	Week 12	137	4.63	0.99	2.6	3.9	4.6	5.3	7.4
	Week 16	136	4.69	1.03	2.7	3.9	4.6	5.4	8.0
	Week 20	133	4.69	1.04	2.7	3.9	4.8	5.3	7.6
	Week 24	131	4.71	1.01	2.3	3.9	4.7	5.4	7.3
	End of Treatment	144	4.68	1.02	2.3	3.9	4.7	5.4	7.3

Table 14.3.1-19 Laboratory Tests

Parameter: Urate (mg/dL)

Group	Time	N	Mean	SD	Min	Q1	Median	Q3	Max
	Follow-up Week 4	130	4.87	1.02	2.8	4.1	4.8	5.4	8.7
	End of Follow-up	144	4.80	1.03	2.8	4.1	4.7	5.4	8.7

Table 14.3.1-19 Laboratory Tests

Parameter: Urea Nitrogen (mg/dL)

Group	Time	N	Mean	SD	Min	Q1	Median	Q3	Max
KLH-2109 200 mg	Screening	143	11.07	2.63	6.1	9.3	10.9	12.6	20.9
	Run-in	143	11.22	2.62	6.5	9.5	11.1	12.9	21.5
	Baseline	143	11.50	2.74	5.3	10.0	11.4	12.8	21.9
	Week 4	140	12.37	2.60	6.4	10.5	12.1	14.0	22.3
	Week 8	137	12.61	3.08	6.1	10.6	12.3	14.5	22.6
	Week 12	136	12.27	2.71	6.0	10.4	12.1	13.8	25.2
	Week 16	135	12.33	2.70	7.2	10.5	12.5	13.9	20.1
	Week 20	131	12.43	3.07	5.7	10.2	12.3	14.3	22.7
	Week 24	132	12.32	2.61	5.2	10.7	11.9	14.0	20.4
	End of Treatment	142	12.24	2.63	5.2	10.7	11.8	14.0	20.4
	Follow-up Week 4	116	11.41	2.76	4.5	9.4	11.5	13.1	24.2
	End of Follow-up	142	11.31	2.68	4.5	9.4	11.3	13.0	24.2
Leuprorelin	Screening	144	10.79	2.54	4.9	9.0	10.6	12.4	18.5
	Run-in	144	11.47	3.01	5.7	9.3	11.3	13.3	22.8
	Baseline	144	11.33	3.37	4.3	9.0	10.8	13.3	23.0
	Week 4	140	12.03	3.03	6.1	10.0	11.6	13.4	24.5
	Week 8	140	12.10	3.00	5.4	9.9	12.2	13.8	21.0
	Week 12	137	12.41	3.17	6.7	9.8	11.8	14.4	23.5
	Week 16	136	12.00	2.99	3.4	9.6	11.9	13.6	20.4
	Week 20	133	12.17	3.02	7.3	10.0	11.9	13.4	25.1
	Week 24	131	11.99	2.77	6.1	10.2	11.7	13.4	21.6
	End of Treatment	144	11.95	3.08	3.6	10.0	11.7	13.5	25.7

Table 14.3.1-19 Laboratory Tests

Parameter: Urea Nitrogen (mg/dL)

Group	Time	N	Mean	SD	Min	Q1	Median	Q3	Max
	Follow-up Week 4	130	12.41	3.19	4.7	10.3	12.2	14.8	22.4
	End of Follow-up	144	12.24	3.13	4.7	10.2	11.8	14.5	22.4

Table 14.3.1-19 Laboratory Tests

Parameter: Lactate Dehydrogenase (U/L)

Group	Time	N	Mean	SD	Min	Q1	Median	Q3	Max
KLH-2109 200 mg	Screening	143	156.6	23.6	109	139	154	172	266
	Run-in	143	160.9	33.5	112	143	158	169	405
	Baseline	143	159.0	26.0	113	141	154	173	295
	Week 4	140	169.3	24.3	117	153	165	183	249
	Week 8	137	172.4	26.2	122	157	168	185	258
	Week 12	136	170.4	24.3	122	155	169	182	250
	Week 16	135	174.4	34.3	118	155	169	190	443
	Week 20	131	175.1	32.3	125	155	171	188	386
	Week 24	132	171.8	26.2	119	154	170	186	251
	End of Treatment	142	170.4	26.3	119	151	168	185	251
	Follow-up Week 4	116	165.7	32.1	118	148	160	177	327
	End of Follow-up	142	164.6	31.4	115	145	159	177	327
Leuprorelin	Screening	144	160.5	31.4	88	143	157	174	380
	Run-in	144	162.0	25.9	91	145	160	177	245
	Baseline	144	161.9	27.7	105	141	159	180	259
	Week 4	140	167.5	27.0	107	151	166	183	288
	Week 8	140	173.7	26.9	111	153	170	192	254
	Week 12	137	173.8	28.1	111	155	168	193	318
	Week 16	136	175.3	30.0	109	154	172	196	330
	Week 20	133	178.6	29.2	110	157	173	196	303
	Week 24	131	174.8	27.5	103	157	173	190	273
	End of Treatment	144	174.7	27.5	103	157	173	190	273

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Table 14.3.1-19 Laboratory Tests

Parameter: Lactate Dehydrogenase (U/L)

Group	Time	N	Mean	SD	Min	Q1	Median	Q3	Max
	Follow-up Week 4	130	174.8	28.7	111	156	172	193	301
	End of Follow-up	144	172.9	28.1	111	152	169	190	301

Table 14.3.1-19 Laboratory Tests

Parameter: HDL Cholesterol (mg/dL)

Group	Time	N	Mean	SD	Min	Q1	Median	Q3	Max
KLH-2109 200 mg	Screening	143	68.2	17.7	25	57	67	81	121
	Run-in	143	64.4	15.3	27	53	64	74	102
	Baseline	143	64.7	15.8	27	54	63	76	106
	Week 4	140	69.3	18.7	28	56	69	82	120
	Week 8	137	68.2	17.1	29	56	68	80	122
	Week 12	136	68.1	18.1	25	54	67	77	121
	Week 16	135	69.8	18.3	21	57	67	79	132
	Week 20	131	69.3	18.3	19	57	68	79	128
	Week 24	132	69.6	18.1	26	58	66	81	129
	End of Treatment	142	70.2	17.8	26	58	68	82	129
	Follow-up Week 4	116	65.6	17.4	23	52	67	77	111
	End of Follow-up	142	65.7	16.9	23	53	65	76	118
Leuprorelin	Screening	144	69.9	15.2	43	58	68	81	115
	Run-in	144	65.5	14.6	38	55	64	75	108
	Baseline	144	64.8	14.6	24	55	63	74	118
	Week 4	140	70.2	16.2	38	59	68	81	109
	Week 8	140	69.4	16.5	39	58	68	80	126
	Week 12	137	67.3	15.5	37	56	65	78	128
	Week 16	136	68.9	15.9	32	57	66	80	127
	Week 20	133	69.5	14.5	41	58	67	80	116
	Week 24	131	69.4	15.5	39	57	69	81	122
	End of Treatment	144	68.8	15.9	39	56	68	80	122

Table 14.3.1-19 Laboratory Tests

Parameter: HDL Cholesterol (mg/dL)

Group	Time	N	Mean	SD	Min	Q1	Median	Q3	Max
	Follow-up Week 4	130	69.9	15.7	43	57	70	81	106
	End of Follow-up	144	70.2	16.1	43	57	70	82	109

Table 14.3.1-19 Laboratory Tests

Parameter: LDL Cholesterol (mg/dL)

Group	Time	N	Mean	SD	Min	Q1	Median	Q3	Max
KLH-2109 200 mg	Screening	143	113.1	27.9	23	95	111	130	194
	Run-in	143	109.7	26.5	34	92	107	125	205
	Baseline	143	111.7	26.1	32	93	109	129	183
	Week 4	140	128.8	29.6	32	109	130	148	213
	Week 8	137	128.5	30.8	32	105	127	150	212
	Week 12	136	130.0	29.5	36	109	130	149	229
	Week 16	135	129.5	29.0	35	111	129	151	211
	Week 20	131	131.5	31.3	45	113	129	154	221
	Week 24	132	131.9	29.6	44	111	132	152	225
	End of Treatment	142	130.1	29.7	44	110	131	151	225
	Follow-up Week 4	116	115.0	28.9	30	97	115	128	202
	End of Follow-up	142	113.9	28.0	30	97	113	125	202
Leuprorelin	Screening	144	116.8	29.5	41	96	113	135	198
	Run-in	144	112.6	27.7	47	93	112	129	224
	Baseline	144	111.2	27.7	36	90	110	129	197
	Week 4	140	123.1	30.6	64	103	119	142	226
	Week 8	140	124.2	31.6	40	104	120	140	225
	Week 12	137	122.9	30.3	46	102	120	145	203
	Week 16	136	125.4	32.5	45	104	122	143	240
	Week 20	133	124.7	32.2	46	101	122	144	239
	Week 24	131	124.3	34.4	55	101	120	149	241
	End of Treatment	144	124.3	34.5	55	100	121	148	241

Table 14.3.1-19 Laboratory Tests

Parameter: LDL Cholesterol (mg/dL)

Group	Time	N	Mean	SD	Min	Q1	Median	Q3	Max
	Follow-up Week 4	130	128.3	34.9	42	105	120	148	254
	End of Follow-up	144	126.5	35.1	42	104	120	145	254

Table 14.3.1-19 Laboratory Tests

Parameter: Cholesterol (mg/dL)

Group	Time	N	Mean	SD	Min	Q1	Median	Q3	Max
KLH-2109 200 mg	Screening	143	195.8	30.2	103	174	195	216	283
	Run-in	143	189.4	28.0	99	170	188	207	276
	Baseline	143	191.7	28.4	97	170	192	211	273
	Week 4	140	217.4	33.2	104	194	220	237	304
	Week 8	137	216.3	32.8	118	196	218	237	296
	Week 12	136	219.0	32.2	110	198	222	238	329
	Week 16	135	220.1	31.8	104	202	221	240	307
	Week 20	131	221.8	34.1	115	202	222	244	314
	Week 24	132	221.7	33.6	114	198	221	241	326
	End of Treatment	142	220.1	33.4	114	195	221	240	326
	Follow-up Week 4	116	197.7	31.9	90	180	196	214	293
	End of Follow-up	142	196.4	31.0	90	178	195	213	293
Leuprorelin	Screening	144	201.9	31.8	132	181	198	219	293
	Run-in	144	194.4	31.1	132	173	191	213	312
	Baseline	144	192.9	31.5	111	173	190	213	277
	Week 4	140	211.4	33.2	146	189	209	229	323
	Week 8	140	213.7	35.1	128	191	211	233	320
	Week 12	137	212.1	34.7	134	190	210	235	318
	Week 16	136	215.3	35.2	120	194	215	235	335
	Week 20	133	214.5	34.1	135	191	212	234	331
	Week 24	131	214.3	38.0	125	188	212	234	344
	End of Treatment	144	213.8	37.9	125	187	212	234	344

Table 14.3.1-19 Laboratory Tests

Parameter: Cholesterol (mg/dL)

Group	Time	N	Mean	SD	Min	Q1	Median	Q3	Max
	Follow-up Week 4	130	217.6	37.5	133	192	215	238	352
	End of Follow-up	144	216.1	37.5	133	190	214	238	352

Table 14.3.1-19 Laboratory Tests

Parameter: Triglycerides (mg/dL)

Group	Time	N	Mean	SD	Min	Q1	Median	Q3	Max
KLH-2109 200 mg	Screening	143	81.3	50.4	31	51	67	92	330
	Run-in	143	86.4	61.4	29	51	71	99	453
	Baseline	143	79.7	41.0	28	49	68	99	265
	Week 4	140	103.4	68.2	29	59	84	126	489
	Week 8	137	102.1	60.7	26	61	91	122	464
	Week 12	136	108.6	67.9	35	64	90	134	409
	Week 16	135	108.9	83.8	28	62	88	128	776
	Week 20	131	113.0	102.3	33	62	90	127	925
	Week 24	132	103.1	61.2	33	62	86	134	430
	End of Treatment	142	100.9	59.8	33	61	85	132	430
	Follow-up Week 4	116	82.9	41.3	27	58	78	94	261
	End of Follow-up	142	81.2	39.4	27	56	74	95	261
Leuprorelin	Screening	144	88.7	53.0	25	53	76	102	279
	Run-in	144	93.5	66.4	18	56	71	109	454
	Baseline	144	90.6	54.6	24	54	77	109	414
	Week 4	140	95.4	49.9	25	60	81	126	287
	Week 8	140	108.7	81.6	24	66	87	124	663
	Week 12	137	115.6	112.2	20	63	86	137	1081
	Week 16	136	109.6	70.2	27	69	86	124	469
	Week 20	133	109.9	62.3	17	69	96	128	346
	Week 24	131	107.5	77.1	24	67	86	114	549
	End of Treatment	144	107.3	75.4	24	68	86	119	549

Table 14.3.1-19 Laboratory Tests

Parameter: Triglycerides (mg/dL)

Group	Time	N	Mean	SD	Min	Q1	Median	Q3	Max
	Follow-up Week 4	130	105.9	66.2	24	67	84	124	440
	End of Follow-up	144	103.7	64.4	17	66	83	121	440

Table 14.3.1-19 Laboratory Tests

Parameter: Urinary Specific Gravity

Group	Time	N	Mean	SD	Min	Q1	Median	Q3	Max
KLH-2109 200 mg	Screening	143	1.0173	0.0086	1.004	1.010	1.017	1.022	1.051
	Run-in	143	1.0161	0.0080	1.003	1.009	1.015	1.022	1.048
	Baseline	143	1.0174	0.0084	1.003	1.010	1.018	1.023	1.048
	Week 4	140	1.0157	0.0068	1.005	1.010	1.016	1.021	1.033
	Week 8	137	1.0153	0.0072	1.003	1.009	1.015	1.021	1.041
	Week 12	136	1.0151	0.0077	1.002	1.010	1.014	1.020	1.050
	Week 16	135	1.0153	0.0076	1.002	1.010	1.015	1.021	1.047
	Week 20	131	1.0148	0.0074	1.004	1.009	1.013	1.020	1.048
	Week 24	132	1.0156	0.0083	1.002	1.009	1.015	1.021	1.055
	End of Treatment	142	1.0156	0.0082	1.002	1.009	1.015	1.021	1.055
	Follow-up Week 4	116	1.0165	0.0082	1.004	1.011	1.016	1.023	1.045
	End of Follow-up	142	1.0167	0.0087	1.004	1.010	1.016	1.023	1.057
Leuprorelin	Screening	144	1.0173	0.0076	1.003	1.011	1.018	1.024	1.032
	Run-in	144	1.0164	0.0077	1.003	1.010	1.018	1.022	1.035
	Baseline	144	1.0161	0.0078	1.003	1.009	1.016	1.023	1.035
	Week 4	140	1.0163	0.0076	1.003	1.010	1.017	1.022	1.032
	Week 8	140	1.0148	0.0072	1.003	1.008	1.014	1.021	1.032
	Week 12	137	1.0166	0.0078	1.003	1.009	1.017	1.022	1.036
	Week 16	136	1.0153	0.0079	1.003	1.009	1.016	1.021	1.042
	Week 20	133	1.0147	0.0073	1.002	1.008	1.015	1.020	1.032
	Week 24	131	1.0148	0.0072	1.003	1.008	1.015	1.021	1.031
	End of Treatment	144	1.0150	0.0071	1.003	1.008	1.015	1.021	1.031

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Table 14.3.1-19 Laboratory Tests

Parameter: Urinary Specific Gravity

Group	Time	N	Mean	SD	Min	Q1	Median	Q3	Max
	Follow-up Week 4	130	1.0162	0.0078	1.003	1.010	1.017	1.022	1.035
	End of Follow-up	144	1.0161	0.0075	1.003	1.010	1.017	1.021	1.035

Table 14.3.1-19 Laboratory Tests

Parameter: Urinary pH

Group	Time	N	Mean	SD	Min	Q1	Median	Q3	Max
KLH-2109 200 mg	Screening	143	6.24	0.74	5.0	5.5	6.0	6.5	8.0
	Run-in	143	6.27	0.73	5.0	5.5	6.0	7.0	8.0
	Baseline	143	6.18	0.69	5.0	5.5	6.0	6.5	8.0
	Week 4	140	6.19	0.73	5.0	5.5	6.0	6.5	8.0
	Week 8	137	6.21	0.78	5.0	5.5	6.0	6.5	8.0
	Week 12	136	6.19	0.68	5.0	5.5	6.3	6.5	7.5
	Week 16	135	6.17	0.76	5.0	5.5	6.0	6.5	8.0
	Week 20	131	6.19	0.81	5.0	5.5	6.0	7.0	8.0
	Week 24	132	6.13	0.70	5.0	5.5	6.0	6.5	8.0
	End of Treatment	142	6.14	0.70	5.0	5.5	6.0	6.5	8.0
	Follow-up Week 4	116	6.18	0.71	5.0	5.5	6.0	6.5	8.0
	End of Follow-up	142	6.19	0.70	5.0	5.5	6.0	6.5	8.0
Leuprorelin	Screening	144	6.39	0.74	5.0	6.0	6.5	7.0	8.0
	Run-in	144	6.18	0.77	5.0	5.5	6.0	6.5	8.5
	Baseline	144	6.18	0.70	5.0	5.5	6.0	6.5	8.0
	Week 4	140	6.16	0.75	5.0	5.5	6.0	6.8	8.0
	Week 8	140	6.28	0.74	5.0	5.5	6.5	6.8	8.0
	Week 12	137	6.14	0.70	5.0	5.5	6.5	6.5	8.0
	Week 16	136	6.21	0.70	5.0	5.5	6.0	6.5	8.0
	Week 20	133	6.16	0.66	5.0	5.5	6.0	6.5	8.0
	Week 24	131	6.23	0.66	5.0	5.5	6.5	6.5	8.0
	End of Treatment	144	6.23	0.66	5.0	5.5	6.5	6.5	8.0

Table 14.3.1-19 Laboratory Tests

Parameter: Urinary pH

Group	Time	N	Mean	SD	Min	Q1	Median	Q3	Max
	Follow-up Week 4	130	6.23	0.70	5.0	5.5	6.0	6.5	8.0
	End of Follow-up	144	6.22	0.70	5.0	5.5	6.0	6.5	8.0

Table 14.3.1-20 Change from Baseline in Laboratory Tests

Parameter: Erythrocytes (10^4/uL)

Group	Time	N	Mean	SD	Min	Q1	Median	Q3	Max
KLH-2109 200 mg	Week 4	140	25.4	25.9	-38	8	23	42	129
	Week 8	137	35.2	31.1	-44	14	32	52	168
	Week 12	135	33.6	34.4	-59	12	32	48	170
	Week 16	135	33.1	33.5	-40	10	31	53	178
	Week 20	131	30.6	33.9	-46	7	26	52	159
	Week 24	132	27.8	31.7	-64	4	28	46	135
	End of Treatment	142	26.9	31.5	-64	4	26	46	135
	Follow-up Week 4	116	10.9	32.6	-95	-9	10	30	178
	End of Follow-up	142	11.8	31.7	-95	-9	11	30	178
Leuprorelin	Week 4	140	26.4	29.3	-49	8	25	42	145
	Week 8	140	41.9	36.6	-46	20	38	62	178
	Week 12	137	39.7	37.8	-34	16	36	55	207
	Week 16	136	40.9	40.1	-33	17	36	59	197
	Week 20	133	36.7	36.2	-24	14	32	53	179
	Week 24	131	33.3	34.5	-27	11	27	52	165
	End of Treatment	144	34.5	35.8	-27	12	27	52	178
	Follow-up Week 4	130	40.4	40.7	-57	15	33	61	225
	End of Follow-up	144	39.6	39.8	-57	16	36	60	225

Table 14.3.1-20 Change from Baseline in Laboratory Tests

Parameter: Leukocytes (/uL)

Group	Time	N	Mean	SD	Min	Q1	Median	Q3	Max
KLH-2109 200 mg	Week 4	140	-620	1020	-3900	-1100	-500	0	3100
	Week 8	137	-410	1130	-3700	-1000	-200	300	2700
	Week 12	135	-500	1080	-5500	-1000	-300	200	1800
	Week 16	135	-330	1090	-4700	-800	-200	300	2400
	Week 20	131	-230	1270	-5000	-600	-100	400	4400
	Week 24	132	-230	1250	-4600	-700	-200	400	4800
	End of Treatment	142	-250	1240	-4600	-800	-200	300	4800
	Follow-up Week 4	116	350	1350	-4200	-300	400	1200	3600
	End of Follow-up	142	330	1340	-4200	-300	300	1200	3600
Leuprorelin	Week 4	140	-300	1270	-5300	-900	-100	300	3400
	Week 8	140	-20	1540	-4800	-500	100	500	9300
	Week 12	137	-190	1300	-5200	-600	-100	500	3000
	Week 16	136	-50	1140	-5000	-500	100	700	3200
	Week 20	133	-30	1420	-5600	-600	200	600	5400
	Week 24	131	-10	1520	-4700	-600	0	600	8900
	End of Treatment	144	-40	1530	-4700	-600	0	600	8900
	Follow-up Week 4	130	-80	1370	-4700	-700	0	600	3600
	End of Follow-up	144	-100	1340	-4700	-700	-100	600	3600

Table 14.3.1-20 Change from Baseline in Laboratory Tests

Parameter: Platelets (10^4/uL)

Group	Time	N	Mean	SD	Min	Q1	Median	Q3	Max
KLH-2109 200 mg	Week 4	140	-1.79	3.22	-12.4	-3.6	-1.8	0.2	9.5
	Week 8	137	-1.48	3.60	-12.6	-3.7	-1.3	0.6	12.8
	Week 12	135	-1.61	3.95	-12.0	-4.2	-1.5	0.5	11.5
	Week 16	135	-1.64	3.87	-11.4	-3.8	-1.9	1.1	10.7
	Week 20	131	-1.48	4.01	-12.8	-3.9	-1.6	1.1	9.8
	Week 24	132	-1.83	3.87	-12.1	-4.4	-1.8	0.4	10.6
	End of Treatment	142	-1.64	3.97	-12.1	-4.1	-1.7	0.5	10.7
	Follow-up Week 4	116	-1.31	4.30	-12.7	-3.8	-1.3	0.8	16.8
	End of Follow-up	142	-1.33	4.26	-15.2	-3.8	-1.2	1.0	16.8
Leuprorelin	Week 4	140	-0.23	4.28	-10.9	-2.2	-0.9	1.6	21.0
	Week 8	140	-2.07	3.72	-13.0	-4.1	-2.0	0.0	9.2
	Week 12	137	-2.11	3.83	-11.8	-5.0	-2.1	0.1	8.2
	Week 16	136	-1.37	3.88	-10.9	-4.1	-1.0	0.8	9.4
	Week 20	133	-1.58	3.98	-11.3	-4.2	-1.6	1.4	10.4
	Week 24	131	-2.06	3.99	-11.4	-4.8	-2.0	0.3	11.3
	End of Treatment	144	-1.97	4.22	-13.0	-4.8	-2.0	0.4	11.3
	Follow-up Week 4	130	-1.94	5.04	-13.3	-5.0	-2.0	0.3	19.4
	End of Follow-up	144	-1.98	5.00	-13.3	-5.3	-1.9	0.3	19.4

Table 14.3.1-20 Change from Baseline in Laboratory Tests

Parameter: Activated Partial Thromboplastin Time (sec)

Group	Time	N	Mean	SD	Min	Q1	Median	Q3	Max
KLH-2109 200 mg	Week 4	140	1.33	1.98	-3.5	-0.1	1.1	2.4	9.6
	Week 8	137	1.88	2.67	-3.9	0.1	1.4	3.0	13.8
	Week 12	136	2.24	2.80	-4.5	0.2	2.0	3.9	11.3
	Week 16	135	2.47	2.89	-6.4	0.3	2.6	4.4	9.6
	Week 20	131	2.65	2.82	-4.1	0.1	2.3	4.9	10.2
	Week 24	132	3.23	2.98	-4.7	1.0	3.2	5.0	12.6
	End of Treatment	142	3.10	2.99	-4.7	0.5	3.0	5.0	12.6
	Follow-up Week 4	116	2.41	2.76	-4.0	0.6	2.4	4.5	9.9
	End of Follow-up	142	2.39	2.64	-4.0	0.5	2.4	4.2	9.9
Leuprorelin	Week 4	140	1.13	1.86	-7.2	0.2	0.9	2.3	8.5
	Week 8	140	1.70	2.09	-4.8	0.4	1.6	3.0	6.8
	Week 12	137	2.42	2.52	-4.3	1.0	2.1	3.7	15.9
	Week 16	136	2.22	2.91	-7.5	0.3	1.6	4.2	9.7
	Week 20	133	2.64	3.02	-5.5	0.4	2.6	4.7	10.0
	Week 24	130	3.29	3.06	-7.2	1.4	3.3	5.3	12.2
	End of Treatment	144	3.25	3.07	-7.2	1.2	3.3	5.3	12.2
	Follow-up Week 4	130	3.48	3.47	-4.0	1.1	3.3	5.3	22.4
	End of Follow-up	144	3.40	3.36	-4.0	1.2	3.2	5.3	22.4

Table 14.3.1-20 Change from Baseline in Laboratory Tests

Parameter: Prothrombin Time (sec)

Group	Time	N	Mean	SD	Min	Q1	Median	Q3	Max
KLH-2109 200 mg	Week 4	140	-0.14	0.63	-1.9	-0.6	-0.2	0.3	2.0
	Week 8	137	-0.19	0.59	-1.9	-0.5	-0.2	0.2	1.1
	Week 12	136	-0.08	0.69	-1.9	-0.6	-0.1	0.5	1.4
	Week 16	135	0.00	0.64	-2.1	-0.3	0.1	0.4	1.6
	Week 20	131	-0.03	0.61	-1.9	-0.3	-0.1	0.4	1.4
	Week 24	132	0.09	0.56	-1.4	-0.3	0.0	0.4	2.4
	End of Treatment	142	0.06	0.57	-1.4	-0.3	0.0	0.4	2.4
	Follow-up Week 4	116	0.35	0.61	-1.5	0.1	0.3	0.7	1.9
	End of Follow-up	142	0.39	0.63	-1.5	0.1	0.4	0.8	2.0
Leuprorelin	Week 4	140	-0.07	0.58	-1.8	-0.4	-0.1	0.3	1.4
	Week 8	140	-0.10	0.60	-2.0	-0.5	-0.1	0.3	2.5
	Week 12	137	0.03	0.59	-2.0	-0.3	0.0	0.4	2.0
	Week 16	136	0.13	0.62	-1.6	-0.2	0.2	0.5	1.8
	Week 20	133	0.12	0.56	-1.7	-0.2	0.1	0.5	1.3
	Week 24	131	0.20	0.62	-2.9	-0.2	0.3	0.6	1.7
	End of Treatment	144	0.19	0.63	-2.9	-0.2	0.3	0.6	1.7
	Follow-up Week 4	130	0.24	0.58	-1.1	-0.2	0.2	0.6	2.4
	End of Follow-up	144	0.21	0.57	-1.1	-0.2	0.2	0.6	2.4

Table 14.3.1-20 Change from Baseline in Laboratory Tests

Parameter: Prothrombin Intl. Normalized Ratio

Group	Time	N	Mean	SD	Min	Q1	Median	Q3	Max
KLH-2109 200 mg	Week 4	140	-0.012	0.055	-0.16	-0.05	-0.01	0.03	0.18
	Week 8	137	-0.018	0.051	-0.17	-0.05	-0.02	0.02	0.10
	Week 12	136	-0.012	0.059	-0.17	-0.05	-0.01	0.03	0.12
	Week 16	135	-0.008	0.055	-0.18	-0.04	0.00	0.03	0.13
	Week 20	131	-0.014	0.054	-0.16	-0.05	-0.02	0.02	0.12
	Week 24	132	-0.007	0.051	-0.15	-0.04	-0.01	0.03	0.16
	End of Treatment	142	-0.009	0.051	-0.15	-0.04	-0.01	0.03	0.16
	Follow-up Week 4	116	0.011	0.054	-0.13	-0.02	0.01	0.04	0.15
	End of Follow-up	142	0.016	0.056	-0.13	-0.02	0.02	0.04	0.18
Leuprorelin	Week 4	140	-0.006	0.050	-0.15	-0.04	-0.01	0.03	0.12
	Week 8	140	-0.009	0.052	-0.17	-0.04	-0.01	0.02	0.22
	Week 12	137	-0.002	0.051	-0.17	-0.04	0.00	0.03	0.17
	Week 16	136	0.003	0.053	-0.14	-0.03	0.00	0.04	0.16
	Week 20	133	-0.002	0.050	-0.15	-0.03	0.00	0.03	0.12
	Week 24	131	0.002	0.055	-0.27	-0.03	0.00	0.04	0.12
	End of Treatment	144	0.002	0.055	-0.27	-0.03	0.01	0.04	0.12
	Follow-up Week 4	130	0.001	0.050	-0.11	-0.04	0.00	0.04	0.16
	End of Follow-up	144	0.000	0.048	-0.11	-0.04	0.00	0.03	0.16

Table 14.3.1-20 Change from Baseline in Laboratory Tests

Parameter: Sodium (mEq/L)

Group	Time	N	Mean	SD	Min	Q1	Median	Q3	Max
KLH-2109 200 mg	Week 4	140	0.8	1.4	-2	0	1	2	4
	Week 8	137	1.0	1.6	-3	0	1	2	6
	Week 12	136	1.1	1.5	-3	0	1	2	6
	Week 16	135	1.0	1.5	-2	0	1	2	5
	Week 20	131	1.3	1.8	-4	0	1	3	6
	Week 24	132	1.1	1.6	-2	0	1	2	7
	End of Treatment	142	1.1	1.6	-2	0	1	2	7
	Follow-up Week 4	116	-0.2	1.8	-4	-2	0	1	4
	End of Follow-up	142	-0.2	1.8	-5	-2	0	1	4
Leuprorelin	Week 4	140	0.7	1.7	-3	0	1	2	5
	Week 8	140	0.9	1.7	-3	0	1	2	6
	Week 12	137	1.3	1.6	-3	0	1	2	6
	Week 16	136	1.3	1.8	-3	0	1	3	6
	Week 20	133	1.4	1.8	-4	0	1	3	6
	Week 24	131	1.6	1.7	-3	0	2	2	7
	End of Treatment	144	1.5	1.7	-3	0	2	2	7
	Follow-up Week 4	130	1.1	1.8	-3	0	1	2	6
	End of Follow-up	144	1.1	1.8	-3	0	1	2	6

Table 14.3.1-20 Change from Baseline in Laboratory Tests

Parameter: Potassium (mEq/L)

Group	Time	N	Mean	SD	Min	Q1	Median	Q3	Max
KLH-2109 200 mg	Week 4	140	-0.01	0.25	-0.7	-0.2	0.0	0.2	0.7
	Week 8	137	0.01	0.29	-1.2	-0.2	0.0	0.2	0.8
	Week 12	136	-0.03	0.27	-0.7	-0.2	0.0	0.1	0.8
	Week 16	135	0.00	0.29	-0.9	-0.2	0.0	0.2	0.7
	Week 20	131	0.04	0.31	-1.0	-0.1	0.0	0.2	1.0
	Week 24	132	-0.05	0.28	-0.9	-0.2	0.0	0.1	0.6
	End of Treatment	142	-0.04	0.28	-0.9	-0.2	0.0	0.1	0.6
	Follow-up Week 4	116	-0.03	0.29	-0.8	-0.2	0.0	0.2	0.8
	End of Follow-up	142	-0.03	0.31	-0.9	-0.2	0.0	0.1	1.1
Leuprorelin	Week 4	140	0.06	0.26	-0.7	-0.1	0.1	0.2	1.0
	Week 8	140	0.06	0.29	-0.6	-0.2	0.1	0.2	1.0
	Week 12	137	0.00	0.26	-0.9	-0.2	0.0	0.2	0.6
	Week 16	136	0.06	0.25	-0.5	-0.1	0.0	0.2	0.9
	Week 20	133	0.02	0.24	-0.6	-0.1	0.0	0.2	0.8
	Week 24	131	-0.02	0.27	-0.7	-0.2	0.0	0.1	0.8
	End of Treatment	144	-0.02	0.27	-0.7	-0.2	0.0	0.2	0.8
	Follow-up Week 4	130	0.02	0.25	-0.5	-0.1	0.0	0.2	0.8
	End of Follow-up	144	0.03	0.25	-0.5	-0.1	0.1	0.2	0.8

Table 14.3.1-20 Change from Baseline in Laboratory Tests

Parameter: Calcium (mg/dL)

Group	Time	N	Mean	SD	Min	Q1	Median	Q3	Max
KLH-2109 200 mg	Week 4	140	0.34	0.30	-0.7	0.2	0.3	0.6	1.1
	Week 8	137	0.47	0.32	-0.3	0.2	0.4	0.7	1.5
	Week 12	136	0.51	0.30	-0.5	0.3	0.5	0.7	1.2
	Week 16	135	0.54	0.29	-0.2	0.3	0.5	0.7	1.3
	Week 20	131	0.54	0.34	-0.4	0.3	0.6	0.8	1.3
	Week 24	132	0.54	0.30	-0.4	0.3	0.5	0.7	1.5
	End of Treatment	142	0.53	0.31	-0.4	0.3	0.5	0.7	1.5
	Follow-up Week 4	116	0.12	0.27	-0.5	-0.1	0.1	0.3	1.0
	End of Follow-up	142	0.10	0.29	-0.5	-0.1	0.1	0.3	1.0
Leuprorelin	Week 4	140	0.26	0.32	-0.8	0.1	0.3	0.5	1.0
	Week 8	140	0.46	0.29	-0.4	0.3	0.5	0.7	1.2
	Week 12	137	0.46	0.32	-0.8	0.3	0.5	0.7	1.3
	Week 16	136	0.51	0.32	-0.5	0.3	0.5	0.7	1.5
	Week 20	133	0.51	0.31	-0.2	0.3	0.6	0.7	1.1
	Week 24	131	0.47	0.33	-0.3	0.2	0.5	0.7	1.3
	End of Treatment	144	0.46	0.33	-0.3	0.2	0.5	0.7	1.3
	Follow-up Week 4	130	0.46	0.36	-0.6	0.3	0.5	0.7	1.2
	End of Follow-up	144	0.46	0.35	-0.6	0.3	0.5	0.7	1.2

Table 14.3.1-20 Change from Baseline in Laboratory Tests

Parameter: Phosphate (mg/dL)

Group	Time	N	Mean	SD	Min	Q1	Median	Q3	Max
KLH-2109 200 mg	Week 4	140	0.28	0.40	-0.6	0.0	0.3	0.5	1.3
	Week 8	137	0.48	0.45	-1.0	0.2	0.5	0.8	1.6
	Week 12	136	0.54	0.42	-0.5	0.3	0.6	0.9	1.5
	Week 16	135	0.52	0.45	-0.6	0.2	0.6	0.9	1.5
	Week 20	131	0.57	0.50	-0.6	0.2	0.6	0.9	2.0
	Week 24	132	0.53	0.45	-0.5	0.2	0.6	0.9	1.6
	End of Treatment	142	0.52	0.45	-0.5	0.2	0.5	0.9	1.6
	Follow-up Week 4	116	0.16	0.43	-0.9	-0.1	0.2	0.5	1.2
	End of Follow-up	142	0.16	0.44	-1.2	-0.1	0.2	0.5	1.2
Leuprorelin	Week 4	140	0.31	0.44	-0.6	0.0	0.3	0.6	1.4
	Week 8	140	0.44	0.47	-0.7	0.1	0.4	0.7	1.9
	Week 12	137	0.61	0.46	-0.7	0.3	0.6	0.9	2.1
	Week 16	136	0.63	0.44	-0.6	0.3	0.6	0.9	1.8
	Week 20	133	0.63	0.50	-0.9	0.3	0.6	0.9	2.2
	Week 24	131	0.66	0.46	-0.6	0.4	0.7	1.0	1.7
	End of Treatment	144	0.67	0.46	-0.6	0.4	0.7	1.0	1.7
	Follow-up Week 4	130	0.50	0.48	-0.7	0.2	0.5	0.8	1.7
	End of Follow-up	144	0.51	0.49	-0.7	0.2	0.5	0.9	1.7

Table 14.3.1-20 Change from Baseline in Laboratory Tests

Parameter: Creatinine (mg/dL)

Group	Time	N	Mean	SD	Min	Q1	Median	Q3	Max
KLH-2109 200 mg	Week 4	140	0.056	0.050	-0.11	0.03	0.05	0.09	0.21
	Week 8	137	0.058	0.054	-0.09	0.02	0.06	0.10	0.19
	Week 12	136	0.047	0.053	-0.07	0.02	0.05	0.08	0.19
	Week 16	135	0.045	0.050	-0.06	0.01	0.04	0.08	0.20
	Week 20	131	0.045	0.060	-0.10	0.00	0.06	0.08	0.20
	Week 24	132	0.047	0.060	-0.08	0.01	0.05	0.08	0.22
	End of Treatment	142	0.046	0.060	-0.08	0.01	0.05	0.08	0.22
	Follow-up Week 4	116	-0.004	0.050	-0.12	-0.04	-0.01	0.03	0.11
	End of Follow-up	142	-0.002	0.051	-0.12	-0.04	-0.01	0.03	0.11
Leuprorelin	Week 4	140	0.009	0.053	-0.13	-0.03	0.01	0.05	0.18
	Week 8	140	0.014	0.057	-0.18	-0.02	0.02	0.05	0.17
	Week 12	137	0.017	0.055	-0.12	-0.02	0.01	0.05	0.17
	Week 16	136	0.014	0.055	-0.17	-0.02	0.01	0.05	0.17
	Week 20	133	0.008	0.053	-0.12	-0.02	0.01	0.04	0.14
	Week 24	131	0.011	0.053	-0.14	-0.02	0.01	0.04	0.15
	End of Treatment	144	0.008	0.055	-0.17	-0.02	0.01	0.04	0.15
	Follow-up Week 4	130	0.014	0.054	-0.13	-0.02	0.01	0.05	0.15
	End of Follow-up	144	0.012	0.056	-0.17	-0.03	0.01	0.05	0.15

Table 14.3.1-20 Change from Baseline in Laboratory Tests

Parameter: Bilirubin (mg/dL)

Group	Time	N	Mean	SD	Min	Q1	Median	Q3	Max
KLH-2109 200 mg	Week 4	140	0.05	0.19	-0.5	-0.1	0.0	0.2	0.5
	Week 8	137	0.04	0.19	-0.5	-0.1	0.0	0.1	0.6
	Week 12	136	0.08	0.21	-0.5	0.0	0.1	0.2	0.8
	Week 16	135	0.09	0.21	-0.5	0.0	0.1	0.2	0.8
	Week 20	131	0.09	0.22	-0.6	0.0	0.1	0.2	0.8
	Week 24	132	0.10	0.19	-0.5	0.0	0.1	0.2	0.8
	End of Treatment	142	0.10	0.20	-0.5	0.0	0.1	0.2	0.8
	Follow-up Week 4	116	0.12	0.22	-0.6	0.0	0.1	0.3	1.1
	End of Follow-up	142	0.11	0.22	-0.6	0.0	0.1	0.2	1.1
Leuprorelin	Week 4	140	0.06	0.16	-0.4	0.0	0.1	0.2	0.6
	Week 8	140	0.11	0.19	-0.3	0.0	0.1	0.2	0.7
	Week 12	137	0.12	0.20	-0.4	0.0	0.1	0.2	0.9
	Week 16	136	0.17	0.22	-0.2	0.0	0.1	0.3	1.1
	Week 20	133	0.19	0.26	-0.3	0.0	0.2	0.3	1.6
	Week 24	131	0.15	0.23	-0.7	0.0	0.1	0.3	0.9
	End of Treatment	144	0.14	0.23	-0.7	0.0	0.1	0.3	0.9
	Follow-up Week 4	130	0.17	0.21	-0.3	0.0	0.2	0.3	0.6
	End of Follow-up	144	0.16	0.21	-0.5	0.0	0.1	0.3	0.6

Table 14.3.1-20 Change from Baseline in Laboratory Tests

Parameter: Protein (g/dL)

Group	Time	N	Mean	SD	Min	Q1	Median	Q3	Max
KLH-2109 200 mg	Week 4	140	0.32	0.35	-0.5	0.1	0.3	0.6	1.4
	Week 8	137	0.39	0.36	-0.4	0.2	0.4	0.6	1.5
	Week 12	136	0.35	0.37	-0.5	0.1	0.3	0.6	1.5
	Week 16	135	0.39	0.34	-0.5	0.2	0.4	0.6	1.4
	Week 20	131	0.37	0.34	-0.6	0.1	0.4	0.6	1.4
	Week 24	132	0.35	0.34	-0.4	0.1	0.3	0.6	1.7
	End of Treatment	142	0.35	0.34	-0.4	0.1	0.3	0.6	1.7
	Follow-up Week 4	116	0.06	0.32	-0.6	-0.2	0.1	0.2	1.4
	End of Follow-up	142	0.06	0.33	-0.8	-0.2	0.1	0.2	1.4
Leuprorelin	Week 4	140	0.28	0.30	-0.9	0.1	0.3	0.5	1.1
	Week 8	140	0.43	0.34	-0.6	0.2	0.4	0.7	1.4
	Week 12	137	0.34	0.36	-0.8	0.1	0.3	0.5	1.8
	Week 16	136	0.41	0.35	-0.5	0.2	0.4	0.6	1.5
	Week 20	133	0.42	0.36	-0.5	0.2	0.4	0.7	1.7
	Week 24	131	0.35	0.39	-0.7	0.1	0.3	0.5	2.1
	End of Treatment	144	0.35	0.39	-0.7	0.1	0.3	0.5	2.1
	Follow-up Week 4	130	0.38	0.38	-0.7	0.2	0.3	0.6	1.4
	End of Follow-up	144	0.37	0.38	-0.7	0.2	0.3	0.6	1.4

Table 14.3.1-20 Change from Baseline in Laboratory Tests

Parameter: Albumin (g/dL)

Group	Time	N	Mean	SD	Min	Q1	Median	Q3	Max
KLH-2109 200 mg	Week 4	140	0.19	0.20	-0.4	0.1	0.2	0.3	0.7
	Week 8	137	0.22	0.21	-0.3	0.1	0.2	0.3	0.9
	Week 12	136	0.20	0.22	-0.4	0.0	0.2	0.3	0.8
	Week 16	135	0.22	0.20	-0.3	0.1	0.2	0.4	0.7
	Week 20	131	0.21	0.22	-0.6	0.1	0.2	0.4	0.7
	Week 24	132	0.21	0.22	-0.4	0.1	0.2	0.4	1.0
	End of Treatment	142	0.21	0.22	-0.4	0.1	0.2	0.4	1.0
	Follow-up Week 4	116	0.03	0.23	-0.6	-0.1	0.0	0.2	0.6
	End of Follow-up	142	0.02	0.23	-0.6	-0.1	0.0	0.2	0.6
Leuprorelin	Week 4	140	0.18	0.23	-0.6	0.0	0.2	0.3	0.8
	Week 8	140	0.26	0.24	-0.3	0.1	0.3	0.4	1.0
	Week 12	137	0.18	0.24	-0.5	0.0	0.2	0.3	1.1
	Week 16	136	0.24	0.24	-0.3	0.1	0.2	0.4	1.0
	Week 20	133	0.24	0.23	-0.3	0.1	0.2	0.4	0.8
	Week 24	131	0.20	0.25	-0.3	0.0	0.2	0.3	1.2
	End of Treatment	144	0.20	0.25	-0.3	0.0	0.2	0.3	1.2
	Follow-up Week 4	130	0.21	0.26	-0.4	0.0	0.2	0.4	0.7
	End of Follow-up	144	0.21	0.25	-0.4	0.0	0.2	0.4	0.7

Table 14.3.1-20 Change from Baseline in Laboratory Tests

Parameter: Aspartate Aminotransferase (U/L)

Group	Time	N	Mean	SD	Min	Q1	Median	Q3	Max
KLH-2109 200 mg	Week 4	140	4.3	6.0	-14	1	3	6	30
	Week 8	137	7.3	11.8	-17	2	5	9	100
	Week 12	136	6.2	8.3	-16	2	4	8	40
	Week 16	135	7.3	13.1	-14	2	4	9	124
	Week 20	131	6.6	10.1	-11	1	4	9	55
	Week 24	132	7.2	12.6	-6	1	4	9	97
	End of Treatment	142	7.3	12.5	-6	1	4	9	97
	Follow-up Week 4	116	2.4	7.1	-13	-1	2	4	54
	End of Follow-up	142	2.2	6.6	-13	-1	1	4	54
Leuprorelin	Week 4	140	1.8	6.8	-53	-1	1	4	26
	Week 8	140	2.5	6.6	-51	0	2	5	28
	Week 12	137	2.9	6.8	-51	0	2	5	27
	Week 16	136	3.2	6.9	-50	1	3	5	29
	Week 20	133	3.9	8.3	-49	0	3	6	44
	Week 24	131	3.5	7.7	-52	0	3	5	29
	End of Treatment	144	3.5	7.6	-52	0	3	5	29
	Follow-up Week 4	130	3.6	7.9	-54	0	3	6	28
	End of Follow-up	144	3.6	7.7	-54	0	3	6	28

Table 14.3.1-20 Change from Baseline in Laboratory Tests

Parameter: Alanine Aminotransferase (U/L)

Group	Time	N	Mean	SD	Min	Q1	Median	Q3	Max
KLH-2109 200 mg	Week 4	140	8.0	11.9	-13	1	4	11	72
	Week 8	137	13.7	20.4	-25	3	6	16	139
	Week 12	136	12.1	15.7	-21	3	7	13	71
	Week 16	135	13.0	16.8	-10	3	8	18	94
	Week 20	131	12.1	16.7	-15	2	6	18	85
	Week 24	132	13.5	22.3	-10	3	8	16	160
	End of Treatment	142	13.6	22.5	-10	2	7	15	160
	Follow-up Week 4	116	3.9	11.0	-16	-1	2	5	85
	End of Follow-up	142	3.5	10.4	-16	-1	2	5	85
Leuprorelin	Week 4	140	3.6	7.9	-32	0	2	6	40
	Week 8	140	4.3	8.0	-31	0	3	6	43
	Week 12	137	5.4	8.3	-30	1	4	7	48
	Week 16	136	6.1	9.9	-26	1	4	8	62
	Week 20	133	7.2	15.5	-27	1	4	8	121
	Week 24	131	6.5	11.4	-30	0	4	9	56
	End of Treatment	144	6.4	11.3	-30	0	4	8	56
	Follow-up Week 4	130	7.2	14.0	-32	0	4	9	73
	End of Follow-up	144	7.1	13.5	-32	1	4	8	73

Table 14.3.1-20 Change from Baseline in Laboratory Tests

Parameter: Gamma Glutamyl Transferase (U/L)

Group	Time	N	Mean	SD	Min	Q1	Median	Q3	Max
KLH-2109 200 mg	Week 4	140	5.8	11.0	-13	1	3	6	73
	Week 8	137	7.7	15.0	-12	1	3	8	128
	Week 12	136	7.3	13.8	-15	1	4	7	89
	Week 16	135	9.2	23.8	-26	1	4	7	245
	Week 20	131	9.2	19.1	-15	2	4	9	115
	Week 24	132	8.1	12.1	-18	2	5	11	70
	End of Treatment	142	7.8	11.7	-18	2	4	9	70
	Follow-up Week 4	116	3.1	7.8	-20	0	1	4	36
	End of Follow-up	142	2.7	7.2	-20	0	1	4	36
Leuprorelin	Week 4	140	2.4	7.4	-51	0	1	4	26
	Week 8	140	3.9	7.6	-32	1	2	5	37
	Week 12	137	5.1	10.0	-34	0	2	6	59
	Week 16	136	6.4	13.2	-29	1	3	7	93
	Week 20	133	8.2	20.9	-41	1	3	9	200
	Week 24	131	7.6	16.6	-49	1	3	8	112
	End of Treatment	144	7.2	16.0	-49	1	2	8	112
	Follow-up Week 4	130	9.1	21.5	-31	1	3	8	185
	End of Follow-up	144	8.5	20.6	-31	1	3	7	185

Table 14.3.1-20 Change from Baseline in Laboratory Tests

Parameter: Alkaline Phosphatase (U/L)

Group	Time	N	Mean	SD	Min	Q1	Median	Q3	Max
KLH-2109 200 mg	Week 4	140	2.8	7.4	-30	-2	2	7	27
	Week 8	137	5.0	8.6	-46	1	6	9	44
	Week 12	136	6.0	8.3	-37	2	5	10	34
	Week 16	135	9.7	11.1	-24	4	9	15	98
	Week 20	131	11.7	10.4	-43	7	12	17	37
	Week 24	132	12.8	11.2	-36	7	14	18	52
	End of Treatment	142	12.5	11.1	-36	6	14	18	52
	Follow-up Week 4	116	14.4	9.8	-21	8	15	21	38
	End of Follow-up	142	14.1	10.4	-21	8	14	21	43
Leuprorelin	Week 4	140	3.3	6.8	-33	-1	3	6	24
	Week 8	140	5.6	7.6	-19	1	4	11	26
	Week 12	137	8.0	8.2	-22	4	7	12	31
	Week 16	136	11.2	8.9	-11	6	11	17	38
	Week 20	133	13.8	10.7	-33	7	13	21	45
	Week 24	131	15.7	11.3	-32	10	15	20	58
	End of Treatment	144	14.9	11.3	-32	9	14	19	58
	Follow-up Week 4	130	17.5	10.8	-25	12	17	23	53
	End of Follow-up	144	17.2	10.8	-25	11	17	23	53

Table 14.3.1-20 Change from Baseline in Laboratory Tests

Parameter: Creatine Kinase (U/L)

Group	Time	N	Mean	SD	Min	Q1	Median	Q3	Max
KLH-2109 200 mg	Week 4	140	4.4	20.5	-117	-5	4	14	93
	Week 8	137	8.3	33.7	-140	-4	4	17	221
	Week 12	136	4.2	28.8	-140	-5	6	13	177
	Week 16	135	91.7	1018.9	-133	-4	3	16	11839
	Week 20	131	5.4	23.4	-121	-2	5	14	64
	Week 24	132	7.6	25.2	-98	-5	6	18	136
	End of Treatment	142	17.0	118.3	-98	-4	6	18	1386
	Follow-up Week 4	116	2.4	27.2	-75	-12	-2	10	113
	End of Follow-up	142	2.2	30.9	-81	-12	-3	9	181
Leuprorelin	Week 4	140	-5.6	153.7	-1239	-5	4	14	965
	Week 8	140	1.3	138.2	-1233	-3	7	21	567
	Week 12	137	-7.8	130.3	-1230	-6	8	19	130
	Week 16	136	-4.0	139.5	-1229	-7	7	17	438
	Week 20	133	-5.7	132.1	-1210	-2	8	22	252
	Week 24	131	-13.6	131.8	-1209	-7	6	17	75
	End of Treatment	144	-11.8	126.3	-1209	-8	6	17	90
	Follow-up Week 4	130	-4.3	140.0	-1247	-9	8	25	258
	End of Follow-up	144	-2.1	135.7	-1247	-9	8	24	313

Table 14.3.1-20 Change from Baseline in Laboratory Tests

Parameter: Urate (mg/dL)

Group	Time	N	Mean	SD	Min	Q1	Median	Q3	Max
KLH-2109 200 mg	Week 4	140	0.10	0.53	-1.1	-0.3	0.1	0.5	1.5
	Week 8	137	0.18	0.63	-1.4	-0.2	0.1	0.5	2.3
	Week 12	136	0.39	0.57	-1.3	0.0	0.4	0.9	1.6
	Week 16	135	0.39	0.63	-1.2	0.0	0.4	0.8	2.2
	Week 20	131	0.50	0.64	-0.9	0.1	0.5	0.9	2.6
	Week 24	132	0.53	0.68	-0.9	0.1	0.5	0.9	3.5
	End of Treatment	142	0.48	0.70	-1.6	0.0	0.4	0.9	3.5
	Follow-up Week 4	116	0.31	0.66	-1.9	0.0	0.2	0.7	2.3
	End of Follow-up	142	0.33	0.63	-1.9	0.0	0.2	0.7	2.3
Leuprorelin	Week 4	140	0.13	0.57	-1.4	-0.2	0.2	0.4	1.8
	Week 8	140	0.19	0.68	-1.4	-0.3	0.2	0.7	1.6
	Week 12	137	0.23	0.62	-1.3	-0.2	0.3	0.6	1.7
	Week 16	136	0.32	0.66	-1.3	-0.1	0.3	0.7	2.1
	Week 20	133	0.33	0.61	-1.1	0.0	0.3	0.7	2.0
	Week 24	131	0.33	0.65	-2.1	-0.1	0.4	0.8	1.7
	End of Treatment	144	0.32	0.64	-2.1	-0.1	0.4	0.8	1.7
	Follow-up Week 4	130	0.45	0.67	-1.8	0.1	0.5	0.9	2.5
	End of Follow-up	144	0.44	0.68	-1.8	0.1	0.5	0.9	2.5

Table 14.3.1-20 Change from Baseline in Laboratory Tests

Parameter: Urea Nitrogen (mg/dL)

Group	Time	N	Mean	SD	Min	Q1	Median	Q3	Max
KLH-2109 200 mg	Week 4	140	0.82	2.57	-7.8	-0.9	0.9	2.8	8.3
	Week 8	137	1.03	3.02	-6.8	-0.7	0.9	3.1	8.7
	Week 12	136	0.70	2.70	-5.8	-0.9	0.7	2.4	10.6
	Week 16	135	0.77	2.66	-6.6	-1.1	0.8	2.6	7.5
	Week 20	131	0.86	2.84	-6.9	-0.6	0.9	2.6	8.3
	Week 24	132	0.76	2.53	-5.0	-0.8	0.7	2.4	7.9
	End of Treatment	142	0.72	2.55	-5.0	-0.8	0.7	2.3	7.9
	Follow-up Week 4	116	-0.04	2.80	-8.1	-1.7	0.2	1.6	8.8
	End of Follow-up	142	-0.17	2.73	-8.1	-1.9	0.1	1.5	8.8
Leuprorelin	Week 4	140	0.79	2.79	-5.1	-0.9	0.7	2.6	7.9
	Week 8	140	0.77	3.12	-11.9	-1.1	0.5	2.3	10.4
	Week 12	137	1.04	3.14	-9.6	-0.7	1.0	2.8	12.4
	Week 16	136	0.65	3.04	-13.0	-1.2	0.7	2.5	11.6
	Week 20	133	0.80	2.87	-9.7	-0.9	0.8	2.3	8.7
	Week 24	131	0.64	3.27	-10.3	-1.3	0.3	2.7	9.4
	End of Treatment	144	0.61	3.27	-10.3	-1.3	0.3	2.7	9.4
	Follow-up Week 4	130	0.84	3.12	-10.8	-0.9	0.9	2.8	11.6
	End of Follow-up	144	0.91	3.09	-10.8	-0.9	0.9	2.9	11.6

Table 14.3.1-20 Change from Baseline in Laboratory Tests

Parameter: Lactate Dehydrogenase (U/L)

Group	Time	N	Mean	SD	Min	Q1	Median	Q3	Max
KLH-2109 200 mg	Week 4	140	9.8	16.5	-62	3	10	19	53
	Week 8	137	12.7	18.1	-67	5	13	22	68
	Week 12	136	10.5	19.3	-67	1	13	22	89
	Week 16	135	14.4	32.3	-71	3	13	23	307
	Week 20	131	14.8	27.0	-72	1	14	26	221
	Week 24	132	11.5	19.3	-71	0	12	21	59
	End of Treatment	142	11.2	18.9	-71	0	12	20	59
	Follow-up Week 4	116	6.1	29.3	-83	-5	4	14	162
	End of Follow-up	142	5.7	27.5	-83	-5	4	14	162
Leuprorelin	Week 4	140	5.9	18.7	-99	-2	6	14	63
	Week 8	140	12.1	19.9	-92	5	13	25	58
	Week 12	137	12.3	21.2	-85	3	14	22	113
	Week 16	136	13.8	21.8	-84	5	13	23	95
	Week 20	133	16.6	21.5	-72	8	16	26	123
	Week 24	131	12.6	21.4	-87	2	12	22	72
	End of Treatment	144	12.8	22.0	-87	2	12	23	78
	Follow-up Week 4	130	11.9	22.4	-90	1	12	23	115
	End of Follow-up	144	11.0	22.0	-90	1	11	23	115

Table 14.3.1-20 Change from Baseline in Laboratory Tests

Parameter: HDL Cholesterol (mg/dL)

Group	Time	N	Mean	SD	Min	Q1	Median	Q3	Max
KLH-2109 200 mg	Week 4	140	4.8	8.1	-20	-1	5	11	29
	Week 8	137	3.8	7.8	-13	-2	4	9	24
	Week 12	136	3.6	8.2	-17	-2	3	9	27
	Week 16	135	5.4	8.6	-19	-1	5	10	35
	Week 20	131	5.3	9.0	-17	-1	5	11	36
	Week 24	132	5.6	9.2	-13	-1	6	11	36
	End of Treatment	142	5.5	9.1	-13	-1	5	11	36
	Follow-up Week 4	116	1.1	9.2	-23	-5	0	7	25
	End of Follow-up	142	1.1	9.3	-23	-5	0	7	26
Leuprorelin	Week 4	140	5.5	8.6	-23	0	5	11	36
	Week 8	140	4.8	8.0	-19	0	5	9	27
	Week 12	137	2.7	9.3	-34	-3	2	9	32
	Week 16	136	4.0	9.1	-19	-2	4	9	28
	Week 20	133	4.5	10.1	-14	-3	4	11	37
	Week 24	131	4.2	9.9	-31	-1	4	10	31
	End of Treatment	144	4.0	10.0	-31	-2	3	10	31
	Follow-up Week 4	130	5.4	10.3	-30	-2	5	12	28
	End of Follow-up	144	5.4	10.6	-30	-2	5	12	30

Table 14.3.1-20 Change from Baseline in Laboratory Tests

Parameter: LDL Cholesterol (mg/dL)

Group	Time	N	Mean	SD	Min	Q1	Median	Q3	Max
KLH-2109 200 mg	Week 4	140	16.9	17.4	-18	5	14	27	64
	Week 8	137	16.3	19.3	-39	5	14	26	100
	Week 12	136	17.8	19.8	-32	4	18	29	110
	Week 16	135	17.4	18.5	-30	4	17	28	111
	Week 20	131	18.4	21.2	-38	5	18	29	91
	Week 24	132	18.9	19.3	-30	8	17	29	102
	End of Treatment	142	18.5	18.9	-30	7	17	27	102
	Follow-up Week 4	116	3.3	19.8	-44	-7	3	13	118
	End of Follow-up	142	2.2	20.6	-51	-9	1	12	118
Leuprorelin	Week 4	140	10.9	15.7	-48	2	9	19	58
	Week 8	140	12.9	17.4	-23	2	10	24	69
	Week 12	137	11.5	17.8	-32	0	9	22	64
	Week 16	136	14.6	18.2	-37	4	13	26	87
	Week 20	133	13.8	22.3	-87	2	11	26	86
	Week 24	131	13.8	22.3	-86	2	11	25	72
	End of Treatment	144	13.1	22.9	-86	2	12	25	72
	Follow-up Week 4	130	16.1	22.8	-46	3	14	29	86
	End of Follow-up	144	15.3	22.2	-46	2	13	28	86

Table 14.3.1-20 Change from Baseline in Laboratory Tests

Parameter: Cholesterol (mg/dL)

Group	Time	N	Mean	SD	Min	Q1	Median	Q3	Max
KLH-2109 200 mg	Week 4	140	25.5	20.9	-19	10	26	37	76
	Week 8	137	24.3	22.0	-45	11	24	38	95
	Week 12	136	27.1	22.8	-22	12	26	39	111
	Week 16	135	28.2	23.3	-26	14	29	41	120
	Week 20	131	29.2	23.7	-40	16	30	43	103
	Week 24	132	29.2	22.2	-18	15	26	41	104
	End of Treatment	142	28.5	21.9	-18	14	26	40	104
	Follow-up Week 4	116	6.5	23.0	-42	-9	5	19	124
	End of Follow-up	142	4.9	23.4	-42	-10	3	17	124
Leuprorelin	Week 4	140	17.4	19.7	-66	6	16	28	72
	Week 8	140	20.8	19.4	-21	7	17	33	79
	Week 12	137	19.0	20.1	-22	6	17	32	72
	Week 16	136	22.7	22.1	-33	9	23	36	98
	Week 20	133	21.8	26.2	-79	5	20	38	114
	Week 24	131	21.6	26.3	-79	4	21	39	92
	End of Treatment	144	20.9	27.2	-79	4	21	38	92
	Follow-up Week 4	130	23.6	26.3	-50	5	23	39	111
	End of Follow-up	144	23.2	25.8	-50	6	22	39	111

Table 14.3.1-20 Change from Baseline in Laboratory Tests

Parameter: Triglycerides (mg/dL)

Group	Time	N	Mean	SD	Min	Q1	Median	Q3	Max
KLH-2109 200 mg	Week 4	140	23.2	53.6	-73	-2	15	34	399
	Week 8	137	22.2	45.5	-83	-2	17	41	251
	Week 12	136	28.7	54.0	-143	1	17	43	252
	Week 16	135	28.7	72.8	-84	2	20	41	704
	Week 20	131	31.5	85.5	-70	-4	18	42	755
	Week 24	132	21.9	49.9	-105	-3	16	47	248
	End of Treatment	142	21.1	48.9	-105	-2	16	45	248
	Follow-up Week 4	116	4.2	33.3	-104	-14	6	21	135
	End of Follow-up	142	1.5	33.8	-108	-16	4	18	135
Leuprorelin	Week 4	140	4.0	46.5	-259	-14	5	27	127
	Week 8	140	17.8	70.7	-263	-10	10	33	533
	Week 12	137	24.2	102.2	-296	-6	10	32	955
	Week 16	136	18.9	61.6	-320	-5	14	39	322
	Week 20	133	19.5	59.5	-305	-4	15	40	243
	Week 24	131	17.4	61.7	-215	-6	14	34	419
	End of Treatment	144	16.7	60.3	-215	-7	13	33	419
	Follow-up Week 4	130	13.6	62.4	-333	-12	11	36	337
	End of Follow-up	144	13.1	59.6	-333	-12	11	34	337

Table 14.3.1-20 Change from Baseline in Laboratory Tests

Parameter: Urinary Specific Gravity

Group	Time	N	Mean	SD	Min	Q1	Median	Q3	Max
KLH-2109 200 mg	Week 4	140	-0.0018	0.0080	-0.034	-0.006	-0.001	0.004	0.017
	Week 8	137	-0.0022	0.0087	-0.026	-0.007	-0.001	0.002	0.022
	Week 12	136	-0.0024	0.0086	-0.031	-0.008	-0.002	0.004	0.018
	Week 16	135	-0.0022	0.0083	-0.032	-0.007	-0.001	0.004	0.022
	Week 20	131	-0.0028	0.0087	-0.038	-0.008	-0.002	0.004	0.015
	Week 24	132	-0.0020	0.0091	-0.039	-0.006	-0.002	0.004	0.025
	End of Treatment	142	-0.0019	0.0090	-0.039	-0.006	-0.002	0.004	0.025
	Follow-up Week 4	116	-0.0009	0.0097	-0.034	-0.007	-0.002	0.006	0.022
	End of Follow-up	142	-0.0007	0.0099	-0.034	-0.006	-0.001	0.005	0.028
Leuprorelin	Week 4	140	0.0003	0.0078	-0.022	-0.004	0.000	0.005	0.024
	Week 8	140	-0.0012	0.0076	-0.021	-0.007	-0.001	0.004	0.022
	Week 12	137	0.0005	0.0082	-0.024	-0.005	0.000	0.005	0.023
	Week 16	136	-0.0007	0.0073	-0.025	-0.005	-0.001	0.004	0.026
	Week 20	133	-0.0013	0.0072	-0.025	-0.005	-0.001	0.003	0.018
	Week 24	131	-0.0011	0.0072	-0.020	-0.006	-0.001	0.004	0.018
	End of Treatment	144	-0.0011	0.0073	-0.020	-0.006	-0.001	0.004	0.018
	Follow-up Week 4	130	-0.0002	0.0078	-0.023	-0.005	0.000	0.005	0.020
	End of Follow-up	144	0.0000	0.0078	-0.023	-0.005	0.000	0.005	0.020

Table 14.3.1-20 Change from Baseline in Laboratory Tests

Parameter: Urinary pH

Group	Time	N	Mean	SD	Min	Q1	Median	Q3	Max
KLH-2109 200 mg	Week 4	140	0.00	0.76	-2.0	-0.5	0.0	0.5	2.0
	Week 8	137	0.02	0.79	-2.0	-0.5	0.0	0.5	3.0
	Week 12	136	0.00	0.77	-2.5	-0.5	0.0	0.5	2.0
	Week 16	135	-0.03	0.76	-2.5	-0.5	0.0	0.5	2.5
	Week 20	131	-0.01	0.82	-2.0	-0.5	0.0	0.5	2.5
	Week 24	132	-0.07	0.83	-2.0	-0.5	0.0	0.5	2.0
	End of Treatment	142	-0.05	0.82	-2.0	-0.5	0.0	0.5	2.0
	Follow-up Week 4	116	0.02	0.71	-2.0	-0.5	0.0	0.5	1.5
	End of Follow-up	142	0.00	0.75	-2.0	-0.5	0.0	0.5	1.5
Leuprorelin	Week 4	140	-0.01	0.78	-2.0	-0.5	0.0	0.5	2.0
	Week 8	140	0.10	0.73	-2.0	-0.5	0.0	0.5	2.0
	Week 12	137	-0.03	0.66	-1.5	-0.5	0.0	0.5	2.0
	Week 16	136	0.04	0.87	-2.0	-0.5	0.0	0.5	2.5
	Week 20	133	-0.01	0.75	-2.5	-0.5	0.0	0.5	2.0
	Week 24	131	0.05	0.79	-2.0	-0.5	0.0	0.5	2.0
	End of Treatment	144	0.05	0.79	-2.0	-0.5	0.0	0.5	2.0
	Follow-up Week 4	130	0.04	0.77	-2.5	-0.5	0.0	0.5	2.0
	End of Follow-up	144	0.04	0.79	-2.5	-0.5	0.0	0.5	2.0

Table 14.3.1-21 Categorical Analysis of Laboratory Tests

Parameter: Urinary Protein

			-		+-		1+		2+		3+		4+		5+	
Group	Time	N	n	%	n	%	n	%	n	%	n	%	n	%	n	%
KLH-2109 200 mg	Screening	143	129	90.2	10	7.0	3	2.1	1	0.7	0	0.0	0	0.0	0	0.0
	Run-in	143	99	69.2	14	9.8	16	11.2	12	8.4	2	1.4	0	0.0	0	0.0
	Baseline	143	98	68.5	24	16.8	15	10.5	5	3.5	1	0.7	0	0.0	0	0.0
	Week 4	140	128	91.4	10	7.1	2	1.4	0	0.0	0	0.0	0	0.0	0	0.0
	Week 8	137	130	94.9	6	4.4	1	0.7	0	0.0	0	0.0	0	0.0	0	0.0
	Week 12	136	129	94.9	5	3.7	2	1.5	0	0.0	0	0.0	0	0.0	0	0.0
	Week 16	135	126	93.3	6	4.4	3	2.2	0	0.0	0	0.0	0	0.0	0	0.0
	Week 20	131	123	93.9	6	4.6	0	0.0	2	1.5	0	0.0	0	0.0	0	0.0
	Week 24	132	119	90.2	12	9.1	1	0.8	0	0.0	0	0.0	0	0.0	0	0.0
	End of Treatment	142	127	89.4	14	9.9	1	0.7	0	0.0	0	0.0	0	0.0	0	0.0
	Follow-up Week 4	116	98	84.5	9	7.8	7	6.0	2	1.7	0	0.0	0	0.0	0	0.0
	End of Follow-up	142	122	85.9	11	7.7	7	4.9	2	1.4	0	0.0	0	0.0	0	0.0
Leuprorelin	Screening	144	129	89.6	15	10.4	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Run-in	144	95	66.0	27	18.8	10	6.9	10	6.9	2	1.4	0	0.0	0	0.0
	Baseline	144	114	79.2	15	10.4	7	4.9	8	5.6	0	0.0	0	0.0	0	0.0
	Week 4	140	129	92.1	11	7.9	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Week 8	140	133	95.0	6	4.3	1	0.7	0	0.0	0	0.0	0	0.0	0	0.0
	Week 12	137	123	89.8	14	10.2	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Week 16	136	127	93.4	8	5.9	1	0.7	0	0.0	0	0.0	0	0.0	0	0.0
	Week 20	133	121	91.0	10	7.5	2	1.5	0	0.0	0	0.0	0	0.0	0	0.0
	Week 24	131	122	93.1	8	6.1	1	0.8	0	0.0	0	0.0	0	0.0	0	0.0
	End of Treatment	144	134	93.1	9	6.3	1	0.7	0	0.0	0	0.0	0	0.0	0	0.0

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Table 14.3.1-21 Categorical Analysis of Laboratory Tests

Parameter: Urinary Protein

			-		+-		1+		2+		3+		4+		5+	
Group	Time	N	n	%	n	%	n	%	n	%	n	%	n	%	n	%
	Follow-up Week 4	130	120	92.3	8	6.2	2	1.5	0	0.0	0	0.0	0	0.0	0	0.0
	End of Follow-up	144	134	93.1	8	5.6	2	1.4	0	0.0	0	0.0	0	0.0	0	0.0

Table 14.3.1-21 Categorical Analysis of Laboratory Tests

Parameter: Urinary Glucose

			-		+-		1+		2+		3+		4+		5+	
Group	Time	N	n	%	n	%	n	%	n	%	n	%	n	%	n	%
KLH-2109 200 mg	Screening	143	139	97.2	1	0.7	0	0.0	0	0.0	3	2.1	0	0.0	0	0.0
	Run-in	143	140	97.9	0	0.0	0	0.0	0	0.0	3	2.1	0	0.0	0	0.0
	Baseline	143	141	98.6	0	0.0	0	0.0	0	0.0	2	1.4	0	0.0	0	0.0
	Week 4	140	139	99.3	0	0.0	0	0.0	0	0.0	1	0.7	0	0.0	0	0.0
	Week 8	137	135	98.5	0	0.0	0	0.0	0	0.0	2	1.5	0	0.0	0	0.0
	Week 12	136	134	98.5	0	0.0	0	0.0	0	0.0	2	1.5	0	0.0	0	0.0
	Week 16	135	133	98.5	0	0.0	0	0.0	0	0.0	2	1.5	0	0.0	0	0.0
	Week 20	131	129	98.5	0	0.0	0	0.0	0	0.0	2	1.5	0	0.0	0	0.0
	Week 24	132	130	98.5	0	0.0	0	0.0	0	0.0	2	1.5	0	0.0	0	0.0
	End of Treatment	142	140	98.6	0	0.0	0	0.0	0	0.0	2	1.4	0	0.0	0	0.0
	Follow-up Week 4	116	115	99.1	0	0.0	0	0.0	0	0.0	1	0.9	0	0.0	0	0.0
	End of Follow-up	142	140	98.6	0	0.0	0	0.0	0	0.0	2	1.4	0	0.0	0	0.0
Leuprorelin	Screening	144	143	99.3	0	0.0	0	0.0	0	0.0	1	0.7	0	0.0	0	0.0
	Run-in	144	140	97.2	1	0.7	1	0.7	0	0.0	2	1.4	0	0.0	0	0.0
	Baseline	144	143	99.3	0	0.0	0	0.0	0	0.0	1	0.7	0	0.0	0	0.0
	Week 4	140	138	98.6	1	0.7	0	0.0	0	0.0	1	0.7	0	0.0	0	0.0
	Week 8	140	139	99.3	0	0.0	0	0.0	0	0.0	1	0.7	0	0.0	0	0.0
	Week 12	137	134	97.8	0	0.0	0	0.0	0	0.0	3	2.2	0	0.0	0	0.0
	Week 16	136	134	98.5	0	0.0	0	0.0	0	0.0	2	1.5	0	0.0	0	0.0
	Week 20	133	131	98.5	0	0.0	0	0.0	1	0.8	1	0.8	0	0.0	0	0.0
	Week 24	131	130	99.2	0	0.0	0	0.0	0	0.0	1	0.8	0	0.0	0	0.0
	End of Treatment	144	143	99.3	0	0.0	0	0.0	0	0.0	1	0.7	0	0.0	0	0.0

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Table 14.3.1-21 Categorical Analysis of Laboratory Tests

Parameter: Urinary Glucose

			-		+-		1+		2+		3+		4+		5+	
Group	Time	N	n	%	n	%	n	%	n	%	n	%	n	%	n	%
	Follow-up Week 4	130	128	98.5	0	0.0	0	0.0	0	0.0	2	1.5	0	0.0	0	0.0
	End of Follow-up	144	142	98.6	0	0.0	0	0.0	0	0.0	2	1.4	0	0.0	0	0.0

Table 14.3.1-21 Categorical Analysis of Laboratory Tests

Parameter: Urinary Urobilinogen

			-		+-		1+		2+		3+		4+		5+	
Group	Time	N	n	%	n	%	n	%	n	%	n	%	n	%	n	%
KLH-2109 200 mg	Screening	143	0	0.0	143	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Run-in	143	0	0.0	143	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Baseline	143	0	0.0	143	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Week 4	140	0	0.0	140	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Week 8	137	0	0.0	137	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Week 12	136	0	0.0	136	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Week 16	135	0	0.0	135	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Week 20	131	0	0.0	131	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Week 24	132	0	0.0	131	99.2	1	0.8	0	0.0	0	0.0	0	0.0	0	0.0
	End of Treatment	142	0	0.0	141	99.3	1	0.7	0	0.0	0	0.0	0	0.0	0	0.0
	Follow-up Week 4	116	0	0.0	116	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	End of Follow-up	142	0	0.0	142	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Leuprorelin	Screening	144	0	0.0	143	99.3	1	0.7	0	0.0	0	0.0	0	0.0	0	0.0
	Run-in	144	0	0.0	143	99.3	1	0.7	0	0.0	0	0.0	0	0.0	0	0.0
	Baseline	144	0	0.0	144	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Week 4	140	0	0.0	140	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Week 8	140	0	0.0	140	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Week 12	137	0	0.0	136	99.3	1	0.7	0	0.0	0	0.0	0	0.0	0	0.0
	Week 16	136	0	0.0	136	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Week 20	133	0	0.0	133	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Week 24	131	0	0.0	130	99.2	1	0.8	0	0.0	0	0.0	0	0.0	0	0.0
	End of Treatment	144	0	0.0	143	99.3	1	0.7	0	0.0	0	0.0	0	0.0	0	0.0

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Table 14.3.1-21 Categorical Analysis of Laboratory Tests

Parameter: Urinary Urobilinogen

			-		+-		1+		2+		3+		4+		5+	
Group	Time	N	n	%	n	%	n	%	n	%	n	%	n	%	n	%
	Follow-up Week 4	130	0	0.0	129	99.2	1	0.8	0	0.0	0	0.0	0	0.0	0	0.0
	End of Follow-up	144	0	0.0	143	99.3	1	0.7	0	0.0	0	0.0	0	0.0	0	0.0

Table 14.3.1-21 Categorical Analysis of Laboratory Tests

Parameter: Urinary Ketones

			-		+-		1+		2+		3+		4+		5+	
Group	Time	N	n	%	n	%	n	%	n	%	n	%	n	%	n	%
KLH-2109 200 mg	Screening	143	140	97.9	0	0.0	2	1.4	0	0.0	1	0.7	0	0.0	0	0.0
	Run-in	143	141	98.6	0	0.0	1	0.7	1	0.7	0	0.0	0	0.0	0	0.0
	Baseline	143	141	98.6	0	0.0	1	0.7	1	0.7	0	0.0	0	0.0	0	0.0
	Week 4	140	139	99.3	0	0.0	1	0.7	0	0.0	0	0.0	0	0.0	0	0.0
	Week 8	137	137	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Week 12	136	136	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Week 16	135	135	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Week 20	131	131	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Week 24	132	132	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	End of Treatment	142	142	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Follow-up Week 4	116	114	98.3	0	0.0	1	0.9	1	0.9	0	0.0	0	0.0	0	0.0
	End of Follow-up	142	140	98.6	0	0.0	1	0.7	1	0.7	0	0.0	0	0.0	0	0.0
Leuprorelin	Screening	144	141	97.9	0	0.0	2	1.4	1	0.7	0	0.0	0	0.0	0	0.0
	Run-in	144	142	98.6	0	0.0	2	1.4	0	0.0	0	0.0	0	0.0	0	0.0
	Baseline	144	141	97.9	0	0.0	3	2.1	0	0.0	0	0.0	0	0.0	0	0.0
	Week 4	140	139	99.3	0	0.0	1	0.7	0	0.0	0	0.0	0	0.0	0	0.0
	Week 8	140	139	99.3	0	0.0	1	0.7	0	0.0	0	0.0	0	0.0	0	0.0
	Week 12	137	135	98.5	0	0.0	2	1.5	0	0.0	0	0.0	0	0.0	0	0.0
	Week 16	136	136	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Week 20	133	132	99.2	0	0.0	1	0.8	0	0.0	0	0.0	0	0.0	0	0.0
	Week 24	131	130	99.2	0	0.0	0	0.0	1	0.8	0	0.0	0	0.0	0	0.0
	End of Treatment	144	142	98.6	0	0.0	0	0.0	2	1.4	0	0.0	0	0.0	0	0.0

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Table 14.3.1-21 Categorical Analysis of Laboratory Tests

Parameter: Urinary Ketones

			-		+-		1+		2+		3+		4+		5+	
Group	Time	N	n	%	n	%	n	%	n	%	n	%	n	%	n	%
	Follow-up Week 4	130	130	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	End of Follow-up	144	144	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0

Table 14.3.1-22 Vital Signs and Body Weight

Parameter: Systolic Blood Pressure (mmHg)

Group	Time	N	Mean	SD	Min	Q1	Median	Q3	Max
KLH-2109 200 mg	Screening	143	116.6	15.0	87	106	115	124	169
	Run-in	143	116.7	14.5	84	107	116	125	162
	Baseline	143	115.7	13.5	78	106	116	124	158
	Week 4	140	117.0	13.0	86	108	117	126	168
	Week 8	137	115.7	13.2	80	105	114	124	150
	Week 12	136	116.4	13.6	84	106	116	125	165
	Week 16	135	117.5	15.0	90	108	116	125	193
	Week 20	131	115.8	13.3	82	107	115	123	166
	Week 24	132	115.6	13.6	84	106	114	125	164
	End of Treatment	142	115.2	13.3	84	105	114	124	164
	Follow-up Week 4	116	113.4	13.6	84	102	112	124	154
	End of Follow-up	142	112.7	13.4	80	102	112	122	154
Leuprorelin	Screening	144	118.3	13.9	94	108	117	127	167
	Run-in	144	116.8	14.1	87	108	115	124	161
	Baseline	144	117.3	14.6	87	107	116	127	169
	Week 4	140	117.0	12.9	90	108	117	126	158
	Week 8	140	117.0	14.3	85	107	116	126	163
	Week 12	137	118.0	13.9	81	109	117	126	158
	Week 16	136	116.1	14.5	79	106	115	126	157
	Week 20	133	117.9	14.4	86	108	117	128	156
	Week 24	131	116.8	14.1	94	105	116	128	149
	End of Treatment	144	116.8	13.9	86	106	116	128	149

Table 14.3.1-22 Vital Signs and Body Weight

Parameter: Systolic Blood Pressure (mmHg)

Group	Time	N	Mean	SD	Min	Q1	Median	Q3	Max
	Follow-up Week 4	130	115.6	14.2	84	104	114	126	152
	End of Follow-up	144	115.1	14.2	84	104	114	126	152

Table 14.3.1-22 Vital Signs and Body Weight

Parameter: Diastolic Blood Pressure (mmHg)

Group	Time	N	Mean	SD	Min	Q1	Median	Q3	Max
KLH-2109 200 mg	Screening	143	73.2	12.0	39	65	72	81	103
	Run-in	143	72.8	11.6	49	65	71	82	105
	Baseline	143	73.6	12.8	39	64	73	83	107
	Week 4	140	75.6	11.4	46	68	76	84	104
	Week 8	137	74.8	11.1	44	68	73	83	99
	Week 12	136	74.5	11.6	44	66	74	83	102
	Week 16	135	75.6	11.4	50	68	74	83	108
	Week 20	131	74.9	12.1	45	66	75	83	99
	Week 24	132	75.1	10.9	53	68	73	83	106
	End of Treatment	142	74.9	10.8	53	67	73	83	106
	Follow-up Week 4	116	71.3	11.7	45	63	69	80	98
	End of Follow-up	142	70.9	11.2	45	63	70	78	98
Leuprorelin	Screening	144	73.0	10.9	48	65	73	80	105
	Run-in	144	73.1	10.6	50	66	73	80	107
	Baseline	144	73.1	10.9	46	66	73	81	102
	Week 4	140	74.9	10.7	48	67	74	83	102
	Week 8	140	75.3	10.3	50	67	75	83	99
	Week 12	137	75.9	10.6	54	68	76	84	107
	Week 16	136	75.1	10.5	53	69	74	80	106
	Week 20	133	76.5	11.6	53	68	75	84	115
	Week 24	131	75.0	11.9	54	66	73	83	115
	End of Treatment	144	74.8	11.9	47	66	73	83	115

Table 14.3.1-22 Vital Signs and Body Weight

Parameter: Diastolic Blood Pressure (mmHg)

Group	Time	N	Mean	SD	Min	Q1	Median	Q3	Max
	Follow-up Week 4	130	74.0	11.4	47	66	73	82	107
	End of Follow-up	144	73.7	11.3	47	66	72	81	107

Table 14.3.1-22 Vital Signs and Body Weight

Parameter: Pulse Rate (beats/min)

Group	Time	N	Mean	SD	Min	Q1	Median	Q3	Max
KLH-2109 200 mg	Screening	143	74.4	11.0	52	66	73	81	109
	Run-in	143	75.0	10.5	51	68	75	83	107
	Baseline	143	74.0	9.7	53	66	73	81	99
	Week 4	140	72.3	10.5	52	65	71	79	110
	Week 8	137	73.4	9.8	48	67	72	80	100
	Week 12	136	73.5	9.6	51	67	74	79	108
	Week 16	135	73.8	10.4	53	67	73	78	122
	Week 20	131	74.3	10.3	52	67	73	79	116
	Week 24	132	73.3	11.0	52	65	72	81	120
	End of Treatment	142	73.4	11.1	52	65	72	81	120
	Follow-up Week 4	116	73.7	9.7	53	66	73	80	102
	End of Follow-up	142	74.0	10.0	53	67	73	80	106
Leuprorelin	Screening	144	73.9	10.4	46	67	73	81	103
	Run-in	144	74.8	10.4	43	68	74	82	100
	Baseline	144	73.7	10.7	48	67	72	79	102
	Week 4	140	72.1	10.3	46	65	71	79	107
	Week 8	140	72.2	11.0	43	64	72	79	109
	Week 12	137	71.9	10.5	40	66	72	79	94
	Week 16	136	74.5	10.7	47	67	73	81	104
	Week 20	133	73.1	10.1	42	67	74	79	99
	Week 24	131	72.4	10.5	45	66	72	79	101
	End of Treatment	144	72.3	10.7	45	66	72	78	107

Table 14.3.1-22 Vital Signs and Body Weight

Parameter: Pulse Rate (beats/min)

Group	Time	N	Mean	SD	Min	Q1	Median	Q3	Max
	Follow-up Week 4	130	73.6	9.5	47	67	74	80	101
	End of Follow-up	144	73.3	9.4	47	67	74	79	101

Table 14.3.1-22 Vital Signs and Body Weight

Parameter: Temperature (C)

Group	Time	N	Mean	SD	Min	Q1	Median	Q3	Max
KLH-2109 200 mg	Screening	143	36.45	0.38	35.0	36.2	36.5	36.7	37.2
	Run-in	143	36.33	0.39	35.4	36.1	36.4	36.6	37.1
	Baseline	143	36.31	0.36	35.2	36.1	36.3	36.6	37.1
	Week 4	140	36.23	0.39	35.0	36.0	36.3	36.5	37.0
	Week 8	137	36.27	0.41	35.1	36.0	36.3	36.6	37.3
	Week 12	136	36.23	0.44	35.0	36.0	36.3	36.5	37.2
	Week 16	135	36.24	0.42	35.0	36.0	36.3	36.5	37.0
	Week 20	131	36.27	0.43	34.9	36.0	36.3	36.6	37.0
	Week 24	132	36.23	0.40	34.9	36.0	36.3	36.5	37.0
	End of Treatment	142	36.24	0.40	34.9	36.0	36.3	36.5	37.0
	Follow-up Week 4	116	36.40	0.39	35.0	36.2	36.4	36.7	37.2
	End of Follow-up	142	36.38	0.38	35.0	36.1	36.4	36.7	37.2
Leuprorelin	Screening	144	36.48	0.41	35.3	36.2	36.5	36.8	37.4
	Run-in	144	36.37	0.39	35.0	36.1	36.4	36.7	37.3
	Baseline	144	36.30	0.42	35.0	36.1	36.4	36.6	37.2
	Week 4	140	36.29	0.39	35.0	36.1	36.3	36.6	37.1
	Week 8	140	36.26	0.40	35.1	36.0	36.3	36.6	37.2
	Week 12	137	36.24	0.41	34.6	36.1	36.3	36.5	37.1
	Week 16	136	36.31	0.40	35.2	36.1	36.3	36.6	37.1
	Week 20	133	36.32	0.39	35.1	36.1	36.4	36.6	37.3
	Week 24	131	36.25	0.41	34.9	36.0	36.3	36.5	37.1
	End of Treatment	144	36.26	0.41	34.9	36.0	36.3	36.6	37.1

Table 14.3.1-22 Vital Signs and Body Weight

Parameter: Temperature (C)

Group	Time	N	Mean	SD	Min	Q1	Median	Q3	Max
	Follow-up Week 4	130	36.24	0.40	35.1	36.0	36.3	36.5	37.0
	End of Follow-up	144	36.23	0.40	35.1	36.0	36.3	36.5	37.0

Table 14.3.1-22 Vital Signs and Body Weight

Parameter: Weight (kg)

Group	Time	N	Mean	SD	Min	Q1	Median	Q3	Max
KLH-2109 200 mg	Screening	143	58.88	9.80	41.8	52.1	57.5	64.3	90.3
	Run-in	143	58.90	9.76	41.9	51.7	57.3	63.9	89.8
	Baseline	143	58.90	9.77	42.3	51.7	57.4	64.8	89.4
	Week 4	140	58.38	9.76	41.5	50.6	56.8	64.7	87.6
	Week 8	137	58.20	9.78	41.1	50.8	56.5	64.1	88.8
	Week 12	136	58.29	9.83	41.0	50.9	56.6	64.5	89.1
	Week 16	135	58.49	9.94	40.0	51.2	57.1	64.0	88.7
	Week 20	131	58.94	9.98	41.1	52.2	58.0	64.5	88.2
	Week 24	132	58.89	10.14	40.1	51.6	57.4	64.9	90.2
	End of Treatment	142	58.24	10.15	40.1	51.0	56.5	64.2	90.2
	Follow-up Week 4	116	59.34	10.38	41.7	52.1	57.5	65.1	91.3
	End of Follow-up	142	59.10	10.15	41.7	52.3	57.0	65.0	91.3
Leuprorelin	Screening	144	60.07	10.17	41.2	52.9	59.1	63.9	94.1
	Run-in	144	60.12	10.10	40.7	53.2	58.9	63.8	92.7
	Baseline	144	60.13	10.13	41.3	52.9	58.8	64.6	93.9
	Week 4	140	59.49	10.01	40.1	52.1	58.6	63.3	92.1
	Week 8	140	59.27	9.94	40.2	52.0	58.4	63.4	90.7
	Week 12	137	59.28	9.99	39.8	52.3	58.3	63.8	89.9
	Week 16	136	59.12	10.13	39.5	51.6	58.4	64.2	90.3
	Week 20	133	59.33	10.14	40.0	52.0	58.2	64.1	90.7
	Week 24	131	59.36	10.28	40.8	52.0	58.7	64.2	90.7
	End of Treatment	144	59.40	10.26	40.8	52.1	58.7	64.3	90.7

Table 14.3.1-22 Vital Signs and Body Weight

Parameter: Weight (kg)

Group	Time	N	Mean	SD	Min	Q1	Median	Q3	Max
	Follow-up Week 4	130	59.54	10.75	36.1	52.0	59.1	64.7	92.4
	End of Follow-up	144	59.32	10.52	36.1	52.0	58.7	64.1	92.4

Table 14.3.1-23 Change from Baseline in Vital Signs and Body Weight

Parameter: Systolic Blood Pressure (mmHg)

Group	Time	N	Mean	SD	Min	Q1	Median	Q3	Max
KLH-2109 200 mg	Week 4	140	1.1	10.2	-30	-6	2	8	29
	Week 8	137	-0.2	9.2	-27	-6	0	7	19
	Week 12	136	0.4	10.2	-36	-6	1	7	24
	Week 16	135	1.5	12.1	-30	-5	1	7	62
	Week 20	131	-0.6	10.4	-45	-7	-2	7	27
	Week 24	132	-0.8	11.3	-29	-9	-1	7	33
	End of Treatment	142	-0.5	11.3	-29	-9	0	8	33
	Follow-up Week 4	116	-2.9	11.3	-32	-11	-3	5	27
	End of Follow-up	142	-2.8	11.2	-32	-10	-3	4	34
Leuprorelin	Week 4	140	-0.3	10.8	-38	-7	0	7	35
	Week 8	140	-0.8	10.8	-39	-9	1	6	21
	Week 12	137	0.2	10.4	-26	-7	0	8	27
	Week 16	136	-1.5	11.0	-31	-10	-2	6	28
	Week 20	133	0.1	11.9	-44	-7	1	7	38
	Week 24	131	-1.0	12.4	-35	-9	-1	6	41
	End of Treatment	144	-0.5	12.6	-35	-9	-1	8	41
	Follow-up Week 4	130	-2.1	12.4	-56	-9	-3	5	30
	End of Follow-up	144	-2.2	12.3	-56	-9	-2	5	30

Table 14.3.1-23 Change from Baseline in Vital Signs and Body Weight

Parameter: Diastolic Blood Pressure (mmHg)

Group	Time	N	Mean	SD	Min	Q1	Median	Q3	Max
KLH-2109 200 mg	Week 4	140	1.8	8.8	-42	-3	2	8	25
	Week 8	137	1.1	7.9	-32	-4	1	7	25
	Week 12	136	0.7	8.4	-33	-4	1	6	22
	Week 16	135	1.8	9.0	-36	-4	2	8	25
	Week 20	131	1.0	9.0	-34	-3	2	7	24
	Week 24	132	1.2	9.5	-35	-5	1	7	28
	End of Treatment	142	1.2	9.4	-35	-4	1	7	28
	Follow-up Week 4	116	-2.7	9.0	-32	-9	-2	4	22
	End of Follow-up	142	-2.5	8.8	-32	-9	-2	4	22
Leuprorelin	Week 4	140	1.8	6.8	-17	-3	2	6	19
	Week 8	140	1.9	8.4	-21	-3	3	8	24
	Week 12	137	2.5	7.6	-19	-3	3	7	30
	Week 16	136	1.7	8.3	-22	-3	2	7	21
	Week 20	133	2.9	8.4	-16	-2	2	8	31
	Week 24	131	1.5	8.2	-21	-4	2	7	25
	End of Treatment	144	1.7	8.2	-21	-4	2	7	25
	Follow-up Week 4	130	0.8	9.1	-34	-4	2	7	20
	End of Follow-up	144	0.6	8.9	-34	-4	2	6	20

Table 14.3.1-23 Change from Baseline in Vital Signs and Body Weight

Parameter: Pulse Rate (beats/min)

Group	Time	N	Mean	SD	Min	Q1	Median	Q3	Max
KLH-2109 200 mg	Week 4	140	-1.5	8.2	-22	-6	-3	3	22
	Week 8	137	-0.3	7.8	-18	-5	-1	4	25
	Week 12	136	-0.1	7.9	-22	-6	0	6	17
	Week 16	135	0.2	9.3	-28	-5	1	6	30
	Week 20	131	0.5	9.0	-28	-5	0	5	29
	Week 24	132	-0.5	9.4	-23	-7	-1	6	30
	End of Treatment	142	-0.4	9.5	-23	-7	-1	6	30
	Follow-up Week 4	116	-0.1	7.6	-19	-5	0	4	20
	End of Follow-up	142	0.1	8.3	-28	-5	0	5	22
Leuprorelin	Week 4	140	-1.7	8.0	-21	-8	-2	3	21
	Week 8	140	-1.3	9.5	-31	-8	-2	4	20
	Week 12	137	-1.4	8.8	-25	-8	-1	4	20
	Week 16	136	1.3	8.7	-20	-5	0	7	26
	Week 20	133	-0.1	8.7	-25	-6	0	5	23
	Week 24	131	-1.0	9.7	-23	-6	-2	5	35
	End of Treatment	144	-1.3	10.2	-32	-6	-1	5	35
	Follow-up Week 4	130	-0.4	9.8	-33	-6	0	6	29
	End of Follow-up	144	-0.3	9.6	-33	-6	0	6	29

Table 14.3.1-23 Change from Baseline in Vital Signs and Body Weight

Parameter: Temperature (C)

Group	Time	N	Mean	SD	Min	Q1	Median	Q3	Max
KLH-2109 200 mg	Week 4	140	-0.08	0.38	-1.0	-0.4	-0.1	0.1	1.0
	Week 8	137	-0.04	0.37	-0.7	-0.3	0.0	0.2	0.9
	Week 12	136	-0.08	0.40	-1.3	-0.3	-0.1	0.1	1.1
	Week 16	135	-0.06	0.41	-1.1	-0.3	-0.1	0.2	0.9
	Week 20	131	-0.03	0.41	-1.3	-0.3	0.0	0.3	1.1
	Week 24	132	-0.08	0.40	-1.3	-0.3	-0.1	0.1	1.0
	End of Treatment	142	-0.07	0.40	-1.3	-0.3	-0.1	0.1	1.0
	Follow-up Week 4	116	0.07	0.40	-1.2	-0.1	0.1	0.3	1.4
	End of Follow-up	142	0.07	0.39	-1.2	-0.2	0.1	0.3	1.4
Leuprorelin	Week 4	140	0.00	0.41	-1.2	-0.2	0.0	0.2	1.2
	Week 8	140	-0.04	0.37	-1.0	-0.3	-0.1	0.2	1.1
	Week 12	137	-0.05	0.36	-1.3	-0.3	0.0	0.1	1.0
	Week 16	136	0.02	0.45	-1.3	-0.2	0.0	0.3	1.3
	Week 20	133	0.02	0.39	-1.1	-0.2	0.0	0.3	1.1
	Week 24	131	-0.04	0.42	-1.2	-0.3	0.0	0.3	1.0
	End of Treatment	144	-0.04	0.42	-1.2	-0.3	0.0	0.3	1.0
	Follow-up Week 4	130	-0.06	0.41	-1.2	-0.3	-0.1	0.2	1.0
	End of Follow-up	144	-0.07	0.40	-1.2	-0.3	-0.1	0.2	1.0

Table 14.3.1-23 Change from Baseline in Vital Signs and Body Weight

Parameter: Weight (kg)

Group	Time	N	Mean	SD	Min	Q1	Median	Q3	Max
KLH-2109 200 mg	Week 4	140	-0.70	2.64	-11.5	-1.4	-0.7	-0.1	26.2
	Week 8	137	-1.01	1.45	-11.7	-1.6	-0.9	-0.2	1.7
	Week 12	136	-1.03	1.60	-11.1	-1.8	-0.8	-0.1	2.6
	Week 16	135	-0.88	1.84	-11.7	-1.7	-0.5	0.1	3.4
	Week 20	131	-0.66	1.95	-10.7	-1.7	-0.5	0.5	4.0
	Week 24	132	-0.63	1.99	-11.0	-1.6	-0.4	0.5	4.3
	End of Treatment	142	-0.70	1.99	-11.0	-1.7	-0.4	0.4	4.3
	Follow-up Week 4	116	0.24	2.13	-10.7	-0.8	0.4	1.5	6.2
	End of Follow-up	142	0.19	2.08	-10.7	-0.8	0.4	1.4	6.2
Leuprorelin	Week 4	140	-0.68	0.98	-3.6	-1.2	-0.7	0.0	2.7
	Week 8	140	-0.94	1.41	-9.9	-1.4	-0.9	-0.4	5.3
	Week 12	137	-0.94	1.56	-8.1	-1.7	-1.0	-0.1	6.7
	Week 16	136	-0.90	1.68	-6.7	-1.9	-0.9	0.0	6.5
	Week 20	133	-0.64	1.79	-6.4	-1.7	-0.8	0.4	8.8
	Week 24	131	-0.67	2.02	-5.8	-1.8	-0.8	0.4	10.6
	End of Treatment	144	-0.72	2.02	-6.6	-1.8	-0.8	0.4	10.6
	Follow-up Week 4	130	-0.76	3.14	-25.3	-1.7	-0.7	0.4	13.2
	End of Follow-up	144	-0.80	3.06	-25.3	-1.8	-0.7	0.5	13.2

Table 14.3.1-24 12-Lead Electrocardiogram Parameters

Parameter: RR Interval (msec)

Group	Time	Measurement Time	N	Mean	SD	Min	Q1	Median	Q3	Max
KLH-2109 200 mg	Screening	---	143	949.8	125.9	620	870	952	1034	1313
	Run-in	---	143	958.1	130.2	705	869	952	1034	1280
	Baseline	Pre-dose	143	960.1	126.7	654	869	956	1052	1332
	Day 1	3 hours post-dose	143	969.9	138.3	645	869	970	1062	1370
	Week 2	Pre-dose	139	976.3	127.4	732	882	980	1047	1337
	Week 4	Pre-dose	140	991.0	129.8	700	895	985	1073	1326
	Week 12	Pre-dose	136	978.0	134.7	606	904	958	1038	1418
	Week 24	---	132	980.2	137.0	563	906	960	1071	1333
	End of Treatment	---	143	974.7	134.9	563	895	955	1052	1333
	Follow-up Week 4	---	116	945.7	122.6	681	857	942	1024	1304
	End of Follow-up	---	142	946.0	120.7	681	857	942	1016	1304
Leuprorelin	Screening	---	144	952.4	137.1	642	859	941	1024	1464
	Run-in	---	144	937.4	129.7	631	848	932	1016	1520
	Baseline	Pre-dose	144	949.9	133.1	680	858	937	1039	1395
	Day 1	3 hours post-dose	144	961.8	135.3	666	855	949	1061	1418
	Week 2	Pre-dose	140	954.0	138.4	612	857	938	1029	1429
	Week 4	Pre-dose	140	970.5	146.4	665	879	967	1052	1463
	Week 12	Pre-dose	137	972.1	151.3	679	864	950	1034	1656
	Week 24	---	131	960.9	136.7	612	869	945	1035	1416
	End of Treatment	---	144	961.2	139.5	612	867	949	1046	1416
	Follow-up Week 4	---	130	947.1	128.0	730	857	923	1034	1410
	End of Follow-up	---	144	953.7	128.1	730	869	926	1035	1410

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Table 14.3.1-24 12-Lead Electrocardiogram Parameters

Parameter: PR Interval (msec)

Group	Time	Measurement Time	N	Mean	SD	Min	Q1	Median	Q3	Max
KLH-2109 200 mg	Screening	---	142	150.9	19.7	98	138	152	162	240
	Run-in	---	143	153.8	18.0	103	143	154	164	224
	Baseline	Pre-dose	143	153.0	20.0	103	141	152	164	250
	Day 1	3 hours post-dose	142	151.2	17.5	106	142	151	163	205
	Week 2	Pre-dose	139	152.0	18.7	103	140	152	164	210
	Week 4	Pre-dose	140	151.7	19.0	92	139	150	164	223
	Week 12	Pre-dose	135	151.4	19.3	92	140	152	164	216
	Week 24	---	132	154.3	17.2	118	140	154	164	215
	End of Treatment	---	143	153.1	17.4	118	139	153	164	215
	Follow-up Week 4	---	115	153.2	17.5	104	141	153	162	214
	End of Follow-up	---	141	154.1	17.2	104	143	154	164	214
Leuprorelin	Screening	---	143	159.2	31.5	112	140	156	171	433
	Run-in	---	144	158.3	19.8	116	142	160	173	220
	Baseline	Pre-dose	144	158.0	20.7	117	142	157	172	222
	Day 1	3 hours post-dose	144	158.1	19.7	108	144	158	172	216
	Week 2	Pre-dose	140	158.3	20.2	114	142	157	172	214
	Week 4	Pre-dose	140	158.9	20.9	114	145	158	170	221
	Week 12	Pre-dose	137	159.5	21.0	110	146	158	174	214
	Week 24	---	130	160.2	21.2	119	145	160	174	233
	End of Treatment	---	144	159.9	21.1	119	145	159	174	233
	Follow-up Week 4	---	130	160.3	21.0	120	146	158	174	248
	End of Follow-up	---	144	160.5	20.7	120	146	158	174	248

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Table 14.3.1-24 12-Lead Electrocardiogram Parameters

Parameter: QRS Duration (msec)

Group	Time	Measurement Time	N	Mean	SD	Min	Q1	Median	Q3	Max
KLH-2109 200 mg	Screening	---	143	90.4	11.1	56	84	90	96	142
	Run-in	---	143	89.7	10.8	60	84	90	96	144
	Baseline	Pre-dose	143	89.6	10.4	70	83	90	95	144
	Day 1	3 hours post-dose	143	90.4	10.6	72	84	90	96	148
	Week 2	Pre-dose	139	90.0	10.3	70	82	89	96	138
	Week 4	Pre-dose	140	90.4	10.7	70	84	90	96	140
	Week 12	Pre-dose	136	91.1	10.5	70	84	90	96	146
	Week 24	---	132	90.8	10.7	51	84	90	96	150
	End of Treatment	---	143	90.6	10.5	51	84	90	96	150
	Follow-up Week 4	---	116	90.2	10.4	63	84	90	96	144
	End of Follow-up	---	142	89.7	10.2	63	84	89	96	144
Leuprorelin	Screening	---	144	89.4	7.9	72	84	90	95	111
	Run-in	---	144	88.4	8.9	48	82	89	95	109
	Baseline	Pre-dose	144	88.5	8.9	42	83	90	94	111
	Day 1	3 hours post-dose	144	88.5	11.8	12	82	90	95	110
	Week 2	Pre-dose	140	89.3	8.5	63	84	90	94	112
	Week 4	Pre-dose	140	89.8	8.5	68	84	90	96	110
	Week 12	Pre-dose	137	89.7	8.6	70	83	90	95	115
	Week 24	---	131	90.0	8.7	70	84	90	96	115
	End of Treatment	---	144	90.0	8.6	70	85	90	96	115
	Follow-up Week 4	---	130	90.5	8.3	74	84	90	96	111
	End of Follow-up	---	144	90.1	8.4	70	84	90	96	111

Table 14.3.1-24 12-Lead Electrocardiogram Parameters

Parameter: QT Interval (msec)

Group	Time	Measurement Time	N	Mean	SD	Min	Q1	Median	Q3	Max
KLH-2109 200 mg	Screening	---	143	412.7	28.9	336	388	412	433	486
	Run-in	---	143	415.7	27.6	360	396	413	436	482
	Baseline	Pre-dose	143	417.4	28.0	348	398	416	436	489
	Day 1	3 hours post-dose	143	426.8	31.2	352	406	428	449	494
	Week 2	Pre-dose	139	420.2	26.0	368	402	418	439	495
	Week 4	Pre-dose	140	425.0	28.3	355	404	427	445	490
	Week 12	Pre-dose	136	420.6	26.8	332	402	421	440	495
	Week 24	---	132	419.2	26.9	350	400	422	440	476
	End of Treatment	---	143	418.0	27.1	350	398	421	440	476
	Follow-up Week 4	---	116	409.6	25.3	340	391	410	428	471
	End of Follow-up	---	142	409.9	25.7	340	391	409	428	471
Leuprorelin	Screening	---	144	411.2	28.7	328	390	411	431	494
	Run-in	---	144	410.6	26.1	351	393	413	430	488
	Baseline	Pre-dose	144	414.5	27.8	356	395	415	436	502
	Day 1	3 hours post-dose	144	417.2	29.0	349	398	414	437	514
	Week 2	Pre-dose	140	414.9	28.1	350	396	412	435	488
	Week 4	Pre-dose	140	417.7	29.8	354	395	418	440	502
	Week 12	Pre-dose	137	416.8	28.8	362	396	418	436	516
	Week 24	---	131	414.5	27.7	338	398	412	432	500
	End of Treatment	---	144	414.4	28.4	338	398	412	433	500
	Follow-up Week 4	---	130	411.9	26.8	354	395	410	426	520
	End of Follow-up	---	144	412.5	26.4	354	398	412	426	520

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Table 14.3.1-24 12-Lead Electrocardiogram Parameters

Parameter: Heart Rate (beats/min)

Group	Time	Measurement Time	N	Mean	SD	Min	Q1	Median	Q3	Max
KLH-2109 200 mg	Screening	---	143	64.2	8.9	46	58	63	69	97
	Run-in	---	143	63.7	8.6	46	58	63	69	85
	Baseline	Pre-dose	143	63.5	8.6	45	57	63	69	92
	Day 1	3 hours post-dose	143	63.0	9.5	45	56	62	69	93
	Week 2	Pre-dose	139	62.4	8.2	45	57	61	68	82
	Week 4	Pre-dose	140	61.4	8.2	45	56	61	67	86
	Week 12	Pre-dose	136	62.4	8.6	42	58	63	66	99
	Week 24	---	132	62.6	9.2	45	56	63	67	107
	End of Treatment	---	143	62.9	9.1	45	57	63	67	107
	Follow-up Week 4	---	116	64.4	8.5	46	59	63	70	88
	End of Follow-up	---	142	64.4	8.3	46	59	63	70	88
Leuprorelin	Screening	---	144	64.2	9.0	40	59	64	70	93
	Run-in	---	144	65.1	9.0	39	59	64	71	95
	Baseline	Pre-dose	144	64.4	8.9	43	58	64	70	88
	Day 1	3 hours post-dose	144	63.5	8.9	42	56	63	70	90
	Week 2	Pre-dose	140	64.2	9.2	42	59	64	70	98
	Week 4	Pre-dose	140	63.2	9.5	41	57	62	68	90
	Week 12	Pre-dose	137	62.9	8.8	36	58	63	69	88
	Week 24	---	131	63.6	8.8	42	57	63	69	98
	End of Treatment	---	144	63.6	9.1	42	57	63	70	98
	Follow-up Week 4	---	130	64.4	8.4	42	58	65	70	84
	End of Follow-up	---	144	64.0	8.3	42	58	65	69	84

Table 14.3.1-24 12-Lead Electrocardiogram Parameters

Parameter: QTcF Interval (msec)

Group	Time	Measurement Time	N	Mean	SD	Min	Q1	Median	Q3	Max
KLH-2109 200 mg	Screening	---	143	420.4	18.9	363	409	419	432	475
	Run-in	---	143	422.3	17.3	387	411	420	434	470
	Baseline	Pre-dose	143	423.7	17.3	380	411	422	435	469
	Day 1	3 hours post-dose	143	431.9	18.9	392	417	432	444	484
	Week 2	Pre-dose	139	424.3	18.0	389	414	422	437	471
	Week 4	Pre-dose	140	426.9	18.1	377	414	426	437	476
	Week 12	Pre-dose	136	424.5	17.3	367	414	422	434	471
	Week 24	---	132	422.9	18.8	318	413	422	431	468
	End of Treatment	---	143	422.4	18.8	318	412	422	431	468
	Follow-up Week 4	---	116	417.9	15.9	380	408	417	428	463
	End of Follow-up	---	142	418.1	16.0	380	408	417	429	463
Leuprorelin	Screening	---	144	418.6	17.6	376	410	419	429	468
	Run-in	---	144	420.2	15.9	370	409	421	430	459
	Baseline	Pre-dose	144	422.3	17.2	374	412	423	435	459
	Day 1	3 hours post-dose	144	423.3	16.8	384	412	423	436	468
	Week 2	Pre-dose	140	422.2	17.1	384	411	421	431	470
	Week 4	Pre-dose	140	422.7	17.1	379	410	423	434	467
	Week 12	Pre-dose	137	421.6	16.1	378	410	421	433	455
	Week 24	---	131	420.8	16.6	371	412	419	431	471
	End of Treatment	---	144	420.6	16.8	371	411	419	430	471
	Follow-up Week 4	---	130	420.0	16.4	379	411	420	429	469
	End of Follow-up	---	144	419.7	16.1	379	410	420	429	469

Table 14.3.1-30 Bone Metabolism Markers

Parameter: Bone Specific Alkaline Phosphatase (ug/L)

Group	Time	N	Mean	SD	Min	Q1	Median	Q3	Max
KLH-2109 200 mg	Baseline	143	9.79	5.00	4.7	7.7	8.9	10.6	59.3
	Week 12	136	10.23	2.76	5.6	8.5	9.7	11.1	23.7
	Week 24	132	12.23	3.27	6.7	9.9	12.0	13.9	25.1
	End of Treatment	139	12.17	3.26	6.7	9.9	11.9	13.8	25.1
	Follow-up Week 24	120	11.93	3.79	5.8	9.5	11.3	13.2	27.5
Leuprorelin	Baseline	144	9.13	2.67	4.6	7.4	8.4	10.6	18.6
	Week 12	137	10.21	2.60	6.0	8.2	10.1	11.8	20.8
	Week 24	131	12.29	3.16	6.6	10.0	12.0	14.3	21.9
	End of Treatment	143	12.05	3.28	2.1	9.6	11.9	14.2	21.9
	Follow-up Week 24	125	12.53	3.88	6.0	9.8	11.6	15.1	29.6

Table 14.3.1-30 Bone Metabolism Markers

Parameter: Type I Collagen N-Telopeptides (nmol BCE/L)

Group	Time	N	Mean	SD	Min	Q1	Median	Q3	Max
KLH-2109 200 mg	Baseline	124	14.91	4.96	5.7	11.7	13.8	16.9	33.8
	Week 12	68	21.88	8.19	10.1	16.8	20.3	22.8	66.5
	Week 24	25	26.74	8.77	13.0	20.6	23.1	33.4	47.0
	End of Treatment	71	22.79	7.72	10.1	17.3	20.8	25.0	47.0
	Follow-up Week 24	16	12.19	5.69	5.4	8.2	10.8	14.2	24.1
Leuprorelin	Baseline	127	14.70	4.64	6.6	11.7	13.7	17.3	37.0
	Week 12	68	20.50	5.55	11.6	16.6	20.2	22.7	39.2
	Week 24	24	23.34	7.44	14.3	18.0	21.6	27.3	40.2
	End of Treatment	73	20.49	6.17	11.6	16.2	20.0	22.6	40.2
	Follow-up Week 24	17	12.06	7.94	5.4	7.7	9.7	12.1	39.0

Table 14.3.1-30 Bone Metabolism Markers

Parameter: Tartrate-Resistant Acid Phosphatase 5b (mU/dL)

Group	Time	N	Mean	SD	Min	Q1	Median	Q3	Max
KLH-2109 200 mg	Baseline	19	212.5	83.0	123	147	194	251	462
	Week 12	68	465.5	173.8	190	346	436	564	1180
	Week 24	107	490.0	160.1	179	363	456	601	1060
	End of Treatment	110	489.0	158.5	179	363	455	598	1060
	Follow-up Week 24	104	267.5	109.5	71	194	239	326	647
Leuprorelin	Baseline	17	213.2	120.3	79	143	187	213	517
	Week 12	69	430.8	148.3	185	316	410	516	1000
	Week 24	107	492.5	161.4	209	368	478	580	1160
	End of Treatment	114	483.9	165.0	94	368	475	577	1160
	Follow-up Week 24	108	286.2	105.2	115	225	272	345	660

Table 14.3.1-31 Serum NTx - Subjects with serum NTx data at Follow-up Week 24

Parameter: Type I Collagen N-Telopeptides (nmol BCE/L)

Group	Time	N	Mean	SD	Min	Q1	Median	Q3	Max
KLH-2109 200 mg	Baseline	16	15.75	5.57	10.1	11.1	14.6	20.0	29.8
	Week 12	16	26.37	12.46	15.1	19.9	21.7	32.0	66.5
	Week 24	16	27.33	9.83	13.0	20.5	22.4	36.4	47.0
	End of Treatment	16	27.33	9.83	13.0	20.5	22.4	36.4	47.0
	Follow-up Week 24	16	12.19	5.69	5.4	8.2	10.8	14.2	24.1
Leuprorelin	Baseline	17	14.15	5.50	8.2	10.8	12.0	17.9	28.6
	Week 12	17	22.36	5.15	15.8	19.3	20.9	25.2	35.8
	Week 24	16	23.43	7.11	14.9	18.0	21.7	27.3	40.2
	End of Treatment	17	23.70	6.97	14.9	18.1	23.3	27.5	40.2
	Follow-up Week 24	17	12.06	7.94	5.4	7.7	9.7	12.1	39.0

Table 14.3.1-35 Percent Change from Baseline in Bone Mineral Density

Parameter: Bone Mineral Density (g/cm^2)

Group	Time (weeks)	N	Mean	SD	Min	Q1	Median	Q3	Max	Two-sided 95% Confidence Interval of mean	
										Lower	Upper
KLH-2109 200 mg	Week 12	137	-2.6037	2.2624	-10.058	-4.115	-2.319	-1.498	4.228	-2.9859	-2.2214
	Week 24	129	-5.3071	2.9950	-12.282	-7.287	-5.215	-3.362	3.743	-5.8288	-4.7853
	End of Treatment	141	-5.0001	3.1100	-12.282	-7.009	-4.915	-3.240	3.743	-5.5179	-4.4823
	Follow-up Week 24	125	-2.8460	2.8970	-9.943	-4.524	-3.010	-0.641	4.922	-3.3589	-2.3332
Leuprorelin	Week 12	138	-1.7317	2.5097	-11.376	-3.361	-2.026	-0.152	5.097	-2.1542	-1.3093
	Week 24	132	-4.2063	2.9766	-15.000	-6.107	-4.327	-2.488	4.866	-4.7188	-3.6938
	End of Treatment	143	-4.0589	3.0747	-15.000	-5.786	-4.230	-1.893	4.866	-4.5672	-3.5507
	Follow-up Week 24	131	-3.6747	2.8236	-10.974	-5.637	-3.582	-1.932	5.821	-4.1627	-3.1866

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Table 14.3.1-36 T-Score

Parameter: T-Score

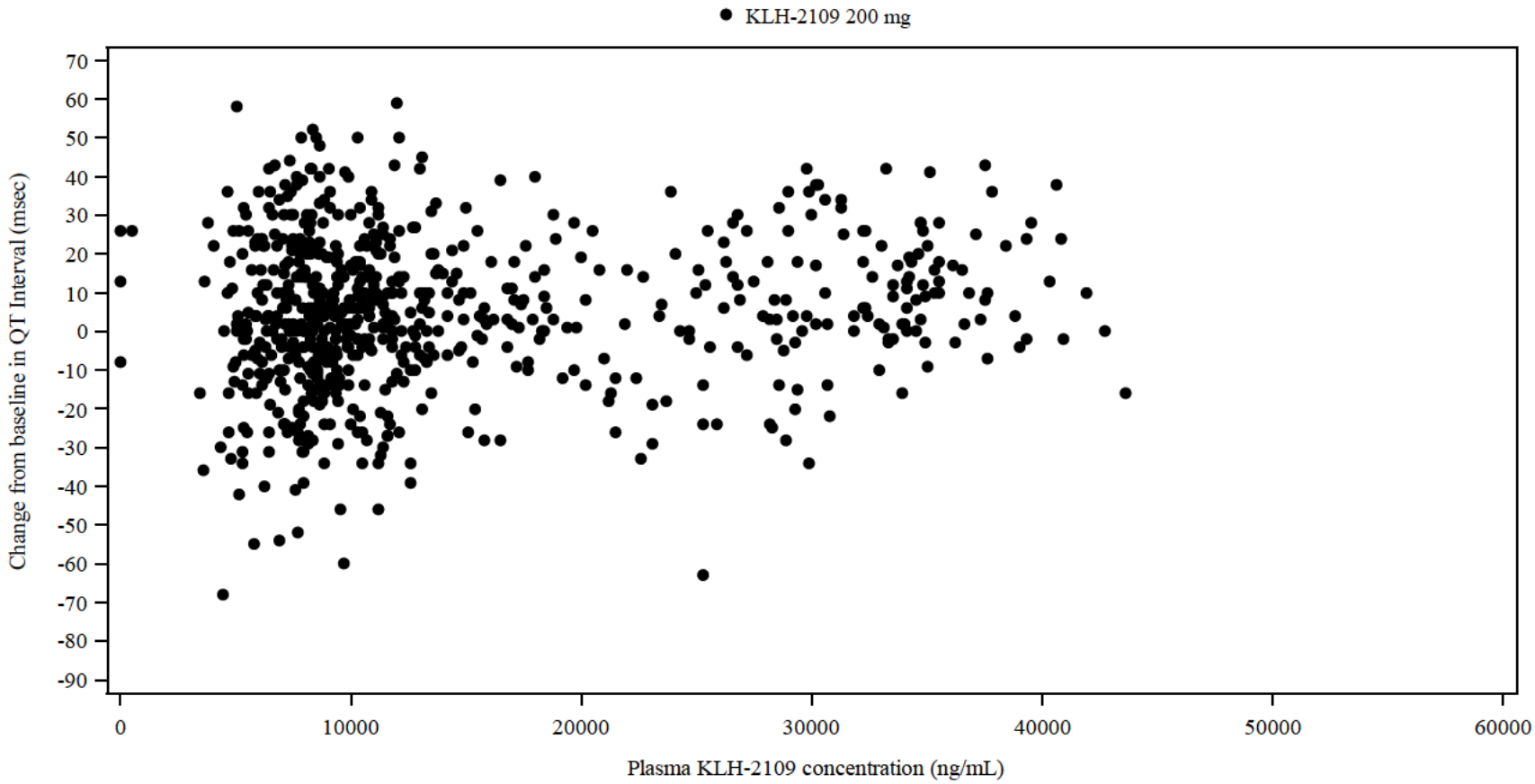
Group	Time	N	Mean	SD	Min	Q1	Median	Q3	Max
KLH-2109 200 mg	Baseline	143	0.41	1.11	-2.4	-0.3	0.3	1.0	4.0
	Week 12	137	0.20	1.14	-2.4	-0.6	0.1	0.9	3.7
	Week 24	129	-0.02	1.16	-2.8	-0.8	-0.1	0.6	3.9
	End of Treatment	141	-0.03	1.12	-2.8	-0.8	-0.1	0.6	3.9
	Follow-up Week 24	125	0.18	1.13	-2.6	-0.6	0.1	0.9	4.0
Leuprorelin	Baseline	144	0.48	1.06	-1.6	-0.3	0.5	1.2	3.4
	Week 12	138	0.33	1.13	-1.8	-0.5	0.3	1.0	3.4
	Week 24	132	0.11	1.10	-2.4	-0.7	0.1	0.9	3.0
	End of Treatment	143	0.11	1.09	-2.4	-0.7	0.1	0.8	3.0
	Follow-up Week 24	131	0.18	1.11	-1.8	-0.7	0.2	1.0	3.0

Table 14.3.1-37 Change from Baseline in T-Score

Parameter: T-Score

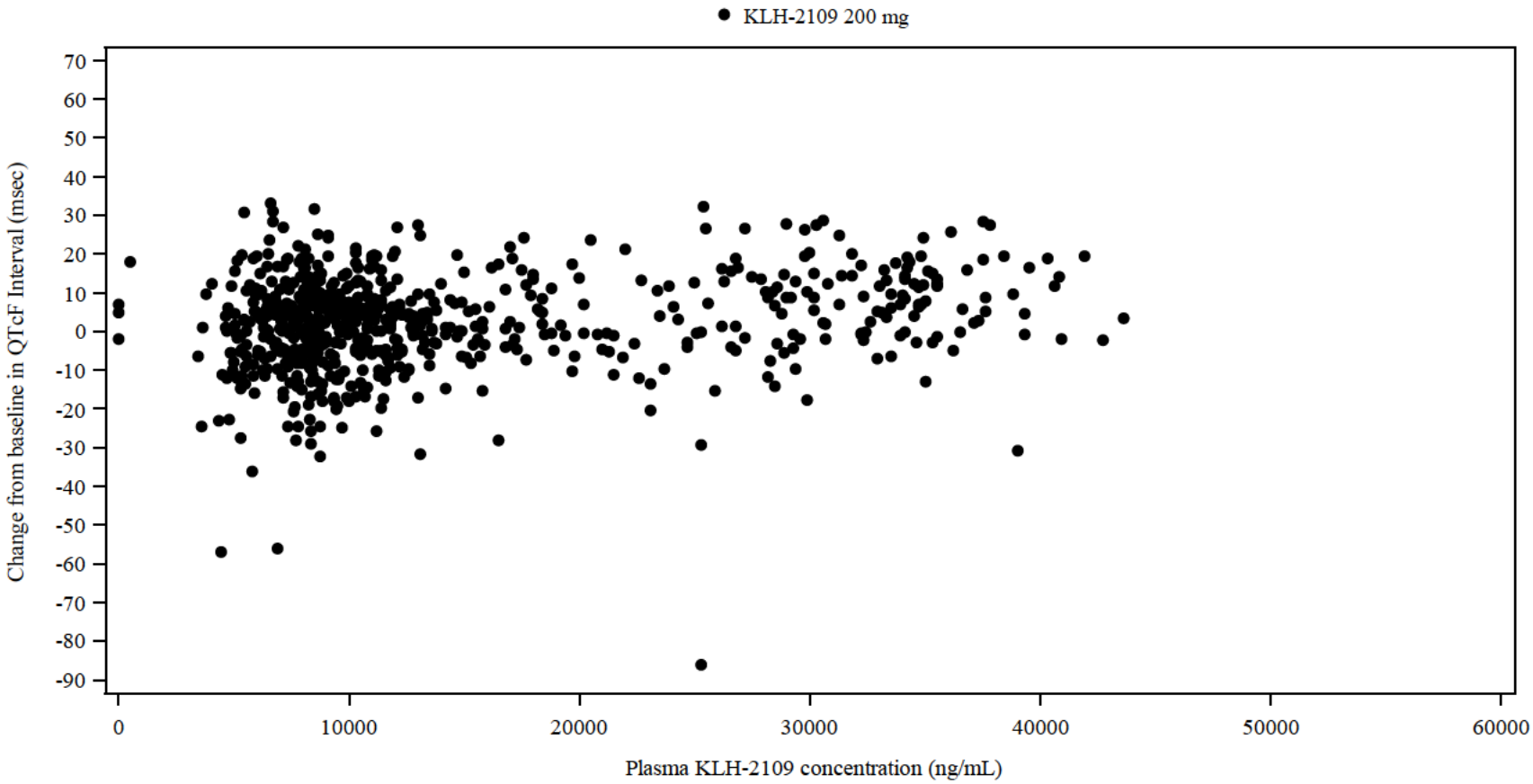
Group	Time	N	Mean	SD	Min	Q1	Median	Q3	Max
KLH-2109 200 mg	Week 12	137	-0.23	0.20	-0.9	-0.4	-0.2	-0.1	0.5
	Week 24	129	-0.47	0.27	-1.1	-0.6	-0.5	-0.3	0.3
	End of Treatment	141	-0.45	0.28	-1.1	-0.6	-0.4	-0.3	0.3
	Follow-up Week 24	125	-0.26	0.27	-0.8	-0.4	-0.3	-0.1	0.5
Leuprorelin	Week 12	138	-0.15	0.23	-1.1	-0.3	-0.2	0.0	0.4
	Week 24	132	-0.38	0.25	-1.1	-0.5	-0.4	-0.2	0.4
	End of Treatment	143	-0.36	0.27	-1.1	-0.5	-0.4	-0.2	0.4
	Follow-up Week 24	131	-0.33	0.26	-1.0	-0.5	-0.3	-0.2	0.6

Figure 14.3.1-1 Scatter Plot of Change from Baseline in QT versus Plasma KLH-2109 Concentrations



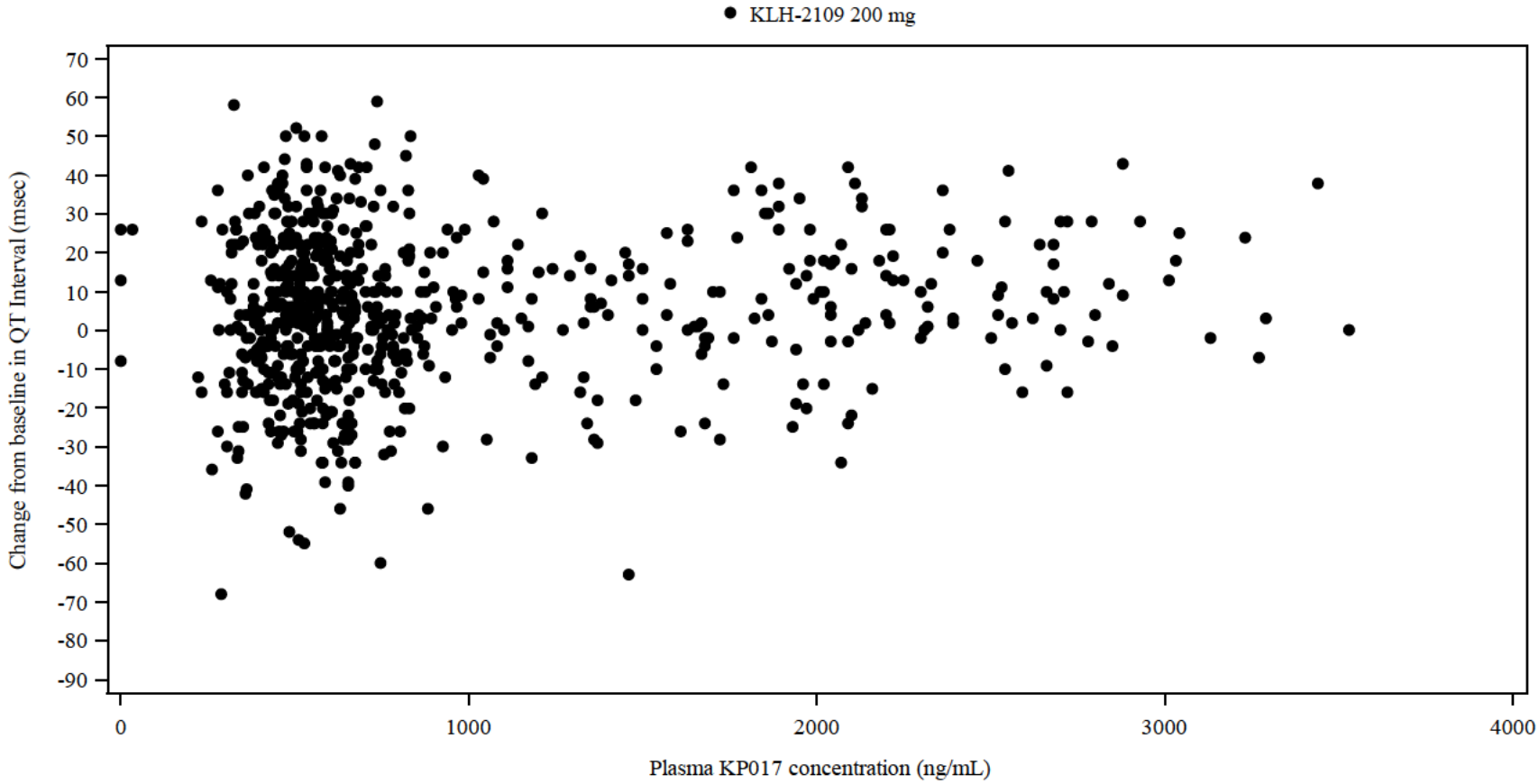
Run Date: 2024-11-07 11:36

Figure 14.3.1-2 Scatter Plot of Change from Baseline in QTcF versus Plasma KLH-2109 Concentrations



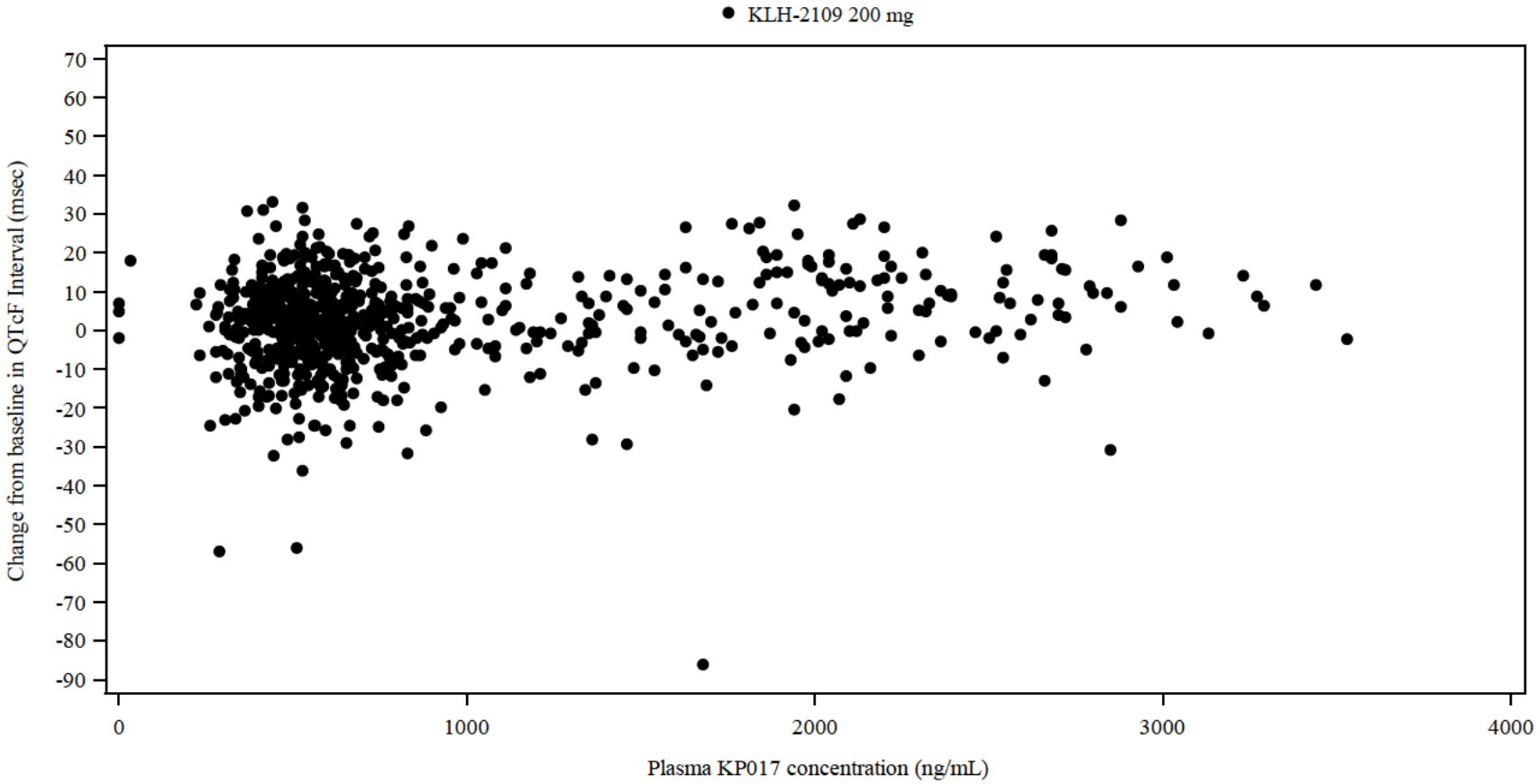
Run Date: 2024-11-07 11:36

Figure 14.3.1-3 Scatter Plot of Change from Baseline in QT versus Plasma KP017 Concentrations



Run Date: 2024-11-07 11:36

Figure 14.3.1-4 Scatter Plot of Change from Baseline in QTcF versus Plasma KP017 Concentrations



Run Date: 2024-11-07 11:36

Table 14.3.1-19 Laboratory Tests

Parameter: Erythrocytes (10^4/uL)

Group	Time	N	Mean	SD	Min	Q1	Median	Q3	Max
KLH-2109 200 mg	Screening	48	428.8	36.9	346	402	432	457	493
	Run-in	48	419.6	38.5	336	387	422	450	487
	Baseline	48	422.5	37.9	332	401	421	448	508
	Week 4	47	450.3	36.6	375	420	454	480	519
	Week 8	47	453.2	38.0	373	425	442	486	522
	Week 12	46	454.2	37.1	383	426	456	480	537
	End of Treatment	48	454.8	37.3	383	427	456	481	537
	Follow-up Week 4	48	430.1	35.9	356	406	428	456	513
	End of Follow-up	48	430.1	35.9	356	406	428	456	513
Placebo	Screening	41	433.8	37.4	341	406	439	458	534
	Run-in	41	420.9	36.2	317	398	426	444	508
	Baseline	41	426.9	35.3	325	404	423	453	513
	Week 4	40	426.0	37.0	341	400	428	452	518
	Week 8	39	434.3	36.2	343	412	443	456	498
	Week 12	40	428.6	45.0	318	396	421	458	546
	End of Treatment	41	428.9	44.5	318	397	421	458	546
	Follow-up Week 4	41	432.1	40.6	353	402	436	451	529
	End of Follow-up	41	432.1	40.6	353	402	436	451	529

Table 14.3.1-19 Laboratory Tests

Parameter: Leukocytes (/uL)

Group	Time	N	Mean	SD	Min	Q1	Median	Q3	Max
KLH-2109 200 mg	Screening	48	5810	1200	3500	5000	5600	6500	9600
	Run-in	48	5770	1580	3100	4600	5400	6500	11600
	Baseline	48	5270	1260	2500	4600	5200	6100	8500
	Week 4	47	5200	1300	3200	4400	4900	6000	9400
	Week 8	47	5020	1430	3100	3900	4800	5500	9600
	Week 12	46	4960	1230	2900	4100	4700	5600	9500
	End of Treatment	48	4960	1210	2900	4200	4700	5600	9500
	Follow-up Week 4	48	5700	1320	3500	4800	5400	6500	9200
	End of Follow-up	48	5700	1320	3500	4800	5400	6500	9200
Placebo	Screening	41	6360	1460	4300	5300	6000	7300	10200
	Run-in	41	6050	1460	3400	5100	5800	6900	10600
	Baseline	41	5290	1220	2900	4400	5000	5600	7900
	Week 4	40	5760	1610	3500	4600	5400	6600	9900
	Week 8	39	6030	1520	3400	5000	5700	7100	9300
	Week 12	40	5840	1420	3200	4900	5700	6400	11500
	End of Treatment	41	5860	1410	3200	4900	5700	6400	11500
	Follow-up Week 4	41	5970	1580	3700	5000	5600	6300	10800
	End of Follow-up	41	5970	1580	3700	5000	5600	6300	10800

Table 14.3.1-19 Laboratory Tests

Parameter: Platelets (10^4/uL)

Group	Time	N	Mean	SD	Min	Q1	Median	Q3	Max
KLH-2109 200 mg	Screening	48	27.93	6.27	15.0	24.3	26.9	32.1	44.5
	Run-in	48	27.58	5.83	11.0	24.6	26.9	30.0	42.9
	Baseline	48	27.46	5.83	14.7	24.0	27.7	30.8	41.7
	Week 4	46	26.30	6.81	13.8	22.5	25.9	28.9	57.1
	Week 8	47	27.38	5.69	16.0	23.3	26.7	30.1	44.0
	Week 12	46	26.52	4.84	14.5	22.9	26.3	29.7	39.8
	End of Treatment	48	26.33	5.06	14.5	22.9	26.3	29.6	39.8
	Follow-up Week 4	48	27.50	5.18	15.5	23.9	27.9	30.9	39.3
	End of Follow-up	48	27.50	5.18	15.5	23.9	27.9	30.9	39.3
Placebo	Screening	41	30.67	7.59	17.4	24.0	29.4	35.4	51.3
	Run-in	41	29.48	7.73	14.4	23.8	27.9	37.0	45.7
	Baseline	41	28.96	7.61	14.8	23.8	27.8	34.5	49.4
	Week 4	40	29.50	7.91	11.7	24.3	29.0	34.0	50.9
	Week 8	39	29.46	7.43	14.2	24.8	28.2	34.8	47.4
	Week 12	40	30.15	7.64	12.1	25.5	29.6	35.4	51.4
	End of Treatment	41	30.12	7.54	12.1	25.6	29.4	34.5	51.4
	Follow-up Week 4	41	30.07	8.58	14.0	25.1	27.9	35.0	54.0
	End of Follow-up	41	30.07	8.58	14.0	25.1	27.9	35.0	54.0

Table 14.3.1-19 Laboratory Tests

Parameter: Activated Partial Thromboplastin Time (sec)

Group	Time	N	Mean	SD	Min	Q1	Median	Q3	Max
KLH-2109 200 mg	Screening	48	31.10	3.10	24.4	28.8	31.1	33.4	39.0
	Run-in	48	31.48	3.48	24.9	28.8	31.3	34.0	41.2
	Baseline	48	31.38	3.51	25.0	28.9	31.6	33.0	40.0
	Week 4	47	32.50	3.86	25.1	29.5	32.1	34.5	42.1
	Week 8	47	32.77	3.36	26.7	30.2	32.8	34.8	41.2
	Week 12	46	33.02	3.05	27.2	30.7	33.1	35.0	40.0
	End of Treatment	48	33.30	3.27	27.2	31.1	33.2	35.1	40.0
	Follow-up Week 4	48	32.41	3.29	24.6	30.1	32.0	34.3	40.8
	End of Follow-up	48	32.41	3.29	24.6	30.1	32.0	34.3	40.8
Placebo	Screening	41	31.92	2.98	26.3	30.1	32.2	33.8	38.9
	Run-in	41	31.95	3.00	25.8	30.5	32.6	33.0	41.2
	Baseline	41	32.21	3.46	26.2	29.7	31.3	34.1	42.0
	Week 4	40	32.42	3.78	26.2	29.7	32.1	34.3	43.3
	Week 8	39	32.52	3.95	25.2	29.4	32.5	35.3	42.3
	Week 12	40	32.83	4.03	24.9	29.3	32.7	36.5	39.6
	End of Treatment	41	32.80	3.99	24.9	29.3	32.5	36.4	39.6
	Follow-up Week 4	41	32.81	3.88	25.6	29.9	32.4	35.8	45.1
	End of Follow-up	41	32.81	3.88	25.6	29.9	32.4	35.8	45.1

Table 14.3.1-19 Laboratory Tests

Parameter: Prothrombin Time (sec)

Group	Time	N	Mean	SD	Min	Q1	Median	Q3	Max
KLH-2109 200 mg	Screening	48	10.81	0.74	9.3	10.3	10.9	11.3	12.9
	Run-in	48	10.88	0.72	9.5	10.4	10.9	11.4	12.4
	Baseline	48	10.77	0.67	9.3	10.3	10.8	11.3	12.1
	Week 4	47	10.87	0.70	9.1	10.3	11.1	11.3	12.2
	Week 8	47	10.79	0.66	9.1	10.3	10.9	11.2	12.2
	Week 12	46	10.88	0.67	9.6	10.4	11.0	11.4	12.1
	End of Treatment	48	10.89	0.65	9.6	10.4	11.0	11.4	12.1
	Follow-up Week 4	48	11.12	0.58	10.1	10.6	11.2	11.5	12.5
	End of Follow-up	48	11.12	0.58	10.1	10.6	11.2	11.5	12.5
Placebo	Screening	41	10.70	0.71	8.9	10.2	10.8	11.2	11.9
	Run-in	41	10.67	0.66	9.3	10.1	10.7	11.2	12.0
	Baseline	41	10.68	0.70	8.8	10.2	10.6	11.2	12.7
	Week 4	40	10.72	0.58	9.7	10.3	10.6	11.2	12.1
	Week 8	39	10.83	0.75	9.4	10.3	10.8	11.4	12.6
	Week 12	40	11.02	0.61	9.9	10.6	11.1	11.6	12.3
	End of Treatment	41	11.01	0.60	9.9	10.6	11.0	11.5	12.3
	Follow-up Week 4	41	10.95	0.67	9.5	10.6	10.9	11.4	12.5
	End of Follow-up	41	10.95	0.67	9.5	10.6	10.9	11.4	12.5

Table 14.3.1-19 Laboratory Tests

Parameter: Prothrombin Intl. Normalized Ratio

Group	Time	N	Mean	SD	Min	Q1	Median	Q3	Max
KLH-2109 200 mg	Screening	48	0.972	0.064	0.84	0.93	0.98	1.02	1.16
	Run-in	48	0.978	0.062	0.86	0.93	0.98	1.03	1.09
	Baseline	48	0.971	0.059	0.84	0.93	0.97	1.02	1.09
	Week 4	47	0.974	0.059	0.83	0.93	0.99	1.01	1.09
	Week 8	47	0.961	0.053	0.83	0.93	0.97	1.00	1.09
	Week 12	46	0.970	0.053	0.87	0.94	0.97	1.01	1.07
	End of Treatment	48	0.970	0.052	0.87	0.94	0.97	1.01	1.07
	Follow-up Week 4	48	0.984	0.049	0.87	0.96	0.98	1.02	1.10
	End of Follow-up	48	0.984	0.049	0.87	0.96	0.98	1.02	1.10
Placebo	Screening	41	0.963	0.060	0.81	0.92	0.97	1.01	1.07
	Run-in	41	0.960	0.057	0.84	0.91	0.97	1.00	1.08
	Baseline	41	0.964	0.061	0.80	0.92	0.96	1.01	1.14
	Week 4	40	0.962	0.049	0.88	0.92	0.96	1.00	1.09
	Week 8	39	0.966	0.061	0.85	0.92	0.96	1.02	1.13
	Week 12	40	0.978	0.047	0.90	0.95	0.97	1.01	1.10
	End of Treatment	41	0.978	0.046	0.90	0.95	0.97	1.00	1.10
	Follow-up Week 4	41	0.971	0.053	0.86	0.93	0.97	1.00	1.08
	End of Follow-up	41	0.971	0.053	0.86	0.93	0.97	1.00	1.08

Table 14.3.1-19 Laboratory Tests

Parameter: Sodium (mEq/L)

Group	Time	N	Mean	SD	Min	Q1	Median	Q3	Max
KLH-2109 200 mg	Screening	48	139.6	1.6	137	138	139	141	143
	Run-in	48	140.1	1.4	138	139	140	141	143
	Baseline	48	140.4	1.4	137	139	141	141	144
	Week 4	47	140.9	1.6	136	140	141	142	144
	Week 8	47	141.0	1.3	138	140	141	142	144
	Week 12	46	141.5	1.8	138	140	141	143	145
	End of Treatment	48	141.4	1.8	138	140	141	143	145
	Follow-up Week 4	48	140.0	1.9	135	139	140	141	144
	End of Follow-up	48	140.0	1.9	135	139	140	141	144
Placebo	Screening	41	139.4	1.4	137	138	139	140	142
	Run-in	41	140.0	1.4	137	139	140	140	145
	Baseline	41	139.8	1.4	137	139	140	141	143
	Week 4	40	139.9	1.7	137	139	140	141	144
	Week 8	39	139.4	1.5	136	138	140	140	143
	Week 12	40	139.2	1.7	136	138	139	141	143
	End of Treatment	41	139.2	1.7	136	138	139	140	143
	Follow-up Week 4	41	139.4	1.5	136	138	139	140	143
	End of Follow-up	41	139.4	1.5	136	138	139	140	143

Table 14.3.1-19 Laboratory Tests

Parameter: Potassium (mEq/L)

Group	Time	N	Mean	SD	Min	Q1	Median	Q3	Max
KLH-2109 200 mg	Screening	48	4.01	0.23	3.6	3.8	4.0	4.2	4.5
	Run-in	48	3.95	0.28	3.3	3.8	3.9	4.2	4.5
	Baseline	48	4.00	0.22	3.5	3.9	4.0	4.2	4.6
	Week 4	47	4.00	0.29	3.3	3.8	4.0	4.2	4.8
	Week 8	47	4.02	0.28	3.5	3.8	4.0	4.2	4.5
	Week 12	46	4.02	0.26	3.4	3.8	4.1	4.2	4.6
	End of Treatment	48	4.03	0.25	3.4	3.9	4.1	4.2	4.6
	Follow-up Week 4	48	4.05	0.30	3.6	3.8	4.0	4.2	5.2
	End of Follow-up	48	4.05	0.30	3.6	3.8	4.0	4.2	5.2
Placebo	Screening	41	4.05	0.33	3.7	3.8	4.0	4.1	5.1
	Run-in	41	4.05	0.30	3.6	3.9	4.0	4.1	5.3
	Baseline	41	4.07	0.29	3.4	3.9	4.0	4.2	4.8
	Week 4	40	4.06	0.24	3.6	3.9	4.1	4.2	4.9
	Week 8	39	4.03	0.30	3.4	3.8	4.0	4.2	4.9
	Week 12	40	4.05	0.31	3.6	3.9	4.0	4.2	5.1
	End of Treatment	41	4.06	0.32	3.6	3.9	4.0	4.2	5.1
	Follow-up Week 4	41	4.08	0.34	3.6	3.8	4.0	4.2	5.1
	End of Follow-up	41	4.08	0.34	3.6	3.8	4.0	4.2	5.1

Table 14.3.1-19 Laboratory Tests

Parameter: Calcium (mg/dL)

Group	Time	N	Mean	SD	Min	Q1	Median	Q3	Max
KLH-2109 200 mg	Screening	48	9.05	0.27	8.6	8.9	9.0	9.3	9.8
	Run-in	48	8.96	0.27	8.5	8.7	9.0	9.1	9.7
	Baseline	48	8.96	0.23	8.5	8.8	9.0	9.1	9.4
	Week 4	47	9.32	0.28	8.8	9.1	9.3	9.5	9.9
	Week 8	47	9.49	0.26	8.9	9.3	9.4	9.7	10.0
	Week 12	46	9.48	0.28	9.0	9.3	9.4	9.7	10.2
	End of Treatment	48	9.48	0.27	9.0	9.3	9.4	9.7	10.2
	Follow-up Week 4	48	9.03	0.32	8.5	8.8	9.0	9.2	9.8
	End of Follow-up	48	9.03	0.32	8.5	8.8	9.0	9.2	9.8
Placebo	Screening	41	9.20	0.29	8.6	9.0	9.2	9.4	9.9
	Run-in	41	9.09	0.21	8.7	8.9	9.1	9.3	9.5
	Baseline	41	9.11	0.24	8.5	9.0	9.1	9.2	9.6
	Week 4	40	9.12	0.28	8.7	8.9	9.1	9.4	9.6
	Week 8	39	9.18	0.28	8.5	9.0	9.1	9.3	9.9
	Week 12	40	9.17	0.33	8.6	8.9	9.2	9.4	9.9
	End of Treatment	41	9.17	0.33	8.6	8.9	9.2	9.4	9.9
	Follow-up Week 4	41	9.22	0.31	8.3	9.0	9.3	9.4	9.8
	End of Follow-up	41	9.22	0.31	8.3	9.0	9.3	9.4	9.8

Table 14.3.1-19 Laboratory Tests

Parameter: Phosphate (mg/dL)

Group	Time	N	Mean	SD	Min	Q1	Median	Q3	Max
KLH-2109 200 mg	Screening	48	3.54	0.43	2.1	3.3	3.7	3.9	4.2
	Run-in	48	3.57	0.51	2.3	3.3	3.6	3.9	5.2
	Baseline	48	3.59	0.50	2.3	3.3	3.6	4.0	4.8
	Week 4	47	3.86	0.48	3.0	3.5	3.8	4.2	5.0
	Week 8	47	4.01	0.36	3.1	3.8	4.0	4.2	4.8
	Week 12	46	4.13	0.46	2.9	3.8	4.1	4.4	5.0
	End of Treatment	48	4.13	0.46	2.9	3.9	4.1	4.4	5.0
	Follow-up Week 4	48	3.69	0.44	2.9	3.4	3.7	4.0	5.0
	End of Follow-up	48	3.69	0.44	2.9	3.4	3.7	4.0	5.0
Placebo	Screening	41	3.61	0.43	2.5	3.3	3.6	3.9	4.5
	Run-in	41	3.54	0.37	2.5	3.3	3.5	3.8	4.5
	Baseline	41	3.59	0.41	2.5	3.3	3.6	3.9	4.5
	Week 4	40	3.51	0.38	2.8	3.2	3.5	3.9	4.2
	Week 8	39	3.64	0.41	3.0	3.3	3.6	3.9	4.7
	Week 12	40	3.53	0.42	2.9	3.2	3.5	3.8	4.5
	End of Treatment	41	3.54	0.42	2.9	3.2	3.5	3.8	4.5
	Follow-up Week 4	41	3.56	0.34	2.9	3.3	3.6	3.7	4.3
	End of Follow-up	41	3.56	0.34	2.9	3.3	3.6	3.7	4.3

Table 14.3.1-19 Laboratory Tests

Parameter: Creatinine (mg/dL)

Group	Time	N	Mean	SD	Min	Q1	Median	Q3	Max
KLH-2109 200 mg	Screening	48	0.616	0.089	0.44	0.55	0.60	0.68	0.85
	Run-in	48	0.618	0.084	0.44	0.57	0.62	0.67	0.85
	Baseline	48	0.613	0.087	0.42	0.55	0.62	0.67	0.84
	Week 4	47	0.669	0.101	0.40	0.61	0.65	0.75	0.93
	Week 8	47	0.664	0.101	0.48	0.58	0.64	0.72	0.88
	Week 12	46	0.674	0.090	0.50	0.60	0.66	0.73	0.88
	End of Treatment	48	0.669	0.093	0.48	0.60	0.66	0.73	0.88
	Follow-up Week 4	48	0.598	0.089	0.45	0.54	0.59	0.65	0.87
	End of Follow-up	48	0.598	0.089	0.45	0.54	0.59	0.65	0.87
Placebo	Screening	41	0.609	0.080	0.47	0.55	0.59	0.67	0.81
	Run-in	41	0.616	0.090	0.50	0.55	0.61	0.66	0.97
	Baseline	41	0.606	0.086	0.35	0.57	0.60	0.65	0.79
	Week 4	40	0.601	0.091	0.31	0.55	0.60	0.67	0.77
	Week 8	39	0.607	0.089	0.34	0.57	0.61	0.64	0.85
	Week 12	40	0.606	0.091	0.37	0.57	0.60	0.65	0.82
	End of Treatment	41	0.604	0.091	0.37	0.57	0.59	0.65	0.82
	Follow-up Week 4	41	0.608	0.095	0.43	0.55	0.59	0.69	0.78
	End of Follow-up	41	0.608	0.095	0.43	0.55	0.59	0.69	0.78

Table 14.3.1-19 Laboratory Tests

Parameter: Bilirubin (mg/dL)

Group	Time	N	Mean	SD	Min	Q1	Median	Q3	Max
KLH-2109 200 mg	Screening	48	0.59	0.22	0.2	0.4	0.6	0.7	1.1
	Run-in	48	0.59	0.23	0.2	0.4	0.6	0.7	1.3
	Baseline	48	0.54	0.18	0.2	0.4	0.5	0.6	0.9
	Week 4	47	0.59	0.20	0.3	0.4	0.6	0.8	1.0
	Week 8	47	0.61	0.25	0.3	0.5	0.6	0.7	1.7
	Week 12	46	0.66	0.22	0.3	0.5	0.7	0.8	1.4
	End of Treatment	48	0.66	0.21	0.3	0.5	0.7	0.8	1.4
	Follow-up Week 4	48	0.67	0.29	0.3	0.5	0.6	0.8	1.7
	End of Follow-up	48	0.67	0.29	0.3	0.5	0.6	0.8	1.7
Placebo	Screening	41	0.59	0.20	0.3	0.4	0.6	0.6	1.2
	Run-in	41	0.55	0.16	0.3	0.4	0.5	0.6	1.0
	Baseline	41	0.56	0.17	0.3	0.4	0.5	0.6	1.0
	Week 4	40	0.58	0.21	0.3	0.5	0.5	0.7	1.2
	Week 8	39	0.61	0.19	0.3	0.4	0.6	0.8	1.0
	Week 12	40	0.62	0.18	0.3	0.5	0.6	0.7	1.1
	End of Treatment	41	0.62	0.18	0.3	0.5	0.6	0.7	1.1
	Follow-up Week 4	41	0.61	0.21	0.3	0.4	0.6	0.7	1.3
	End of Follow-up	41	0.61	0.21	0.3	0.4	0.6	0.7	1.3

Table 14.3.1-19 Laboratory Tests

Parameter: Protein (g/dL)

Group	Time	N	Mean	SD	Min	Q1	Median	Q3	Max
KLH-2109 200 mg	Screening	48	6.88	0.42	5.9	6.6	6.9	7.1	7.9
	Run-in	48	6.81	0.38	6.0	6.6	6.8	7.1	7.5
	Baseline	48	6.80	0.35	6.2	6.5	6.9	7.0	7.6
	Week 4	47	7.16	0.35	6.4	6.9	7.2	7.4	7.9
	Week 8	47	7.22	0.38	6.3	7.0	7.2	7.4	8.3
	Week 12	46	7.19	0.37	6.5	6.9	7.2	7.5	7.9
	End of Treatment	48	7.20	0.37	6.5	7.0	7.2	7.5	7.9
	Follow-up Week 4	48	6.81	0.34	5.9	6.7	6.8	7.1	7.6
	End of Follow-up	48	6.81	0.34	5.9	6.7	6.8	7.1	7.6
Placebo	Screening	41	7.03	0.32	6.5	6.8	7.1	7.2	7.6
	Run-in	41	6.95	0.30	6.4	6.7	6.9	7.1	7.7
	Baseline	41	6.94	0.35	6.1	6.7	6.9	7.1	7.7
	Week 4	40	6.95	0.36	6.4	6.7	6.9	7.2	7.8
	Week 8	39	7.01	0.33	6.1	6.8	7.1	7.3	7.7
	Week 12	40	6.98	0.37	6.0	6.8	7.0	7.3	7.9
	End of Treatment	41	6.98	0.37	6.0	6.8	7.0	7.2	7.9
	Follow-up Week 4	41	7.02	0.37	6.1	6.8	7.0	7.2	7.8
	End of Follow-up	41	7.02	0.37	6.1	6.8	7.0	7.2	7.8

Table 14.3.1-19 Laboratory Tests

Parameter: Albumin (g/dL)

Group	Time	N	Mean	SD	Min	Q1	Median	Q3	Max
KLH-2109 200 mg	Screening	48	4.17	0.23	3.7	4.1	4.2	4.3	4.7
	Run-in	48	4.13	0.21	3.7	4.0	4.1	4.2	4.8
	Baseline	48	4.12	0.23	3.8	3.9	4.1	4.3	4.7
	Week 4	47	4.31	0.25	3.9	4.1	4.3	4.4	4.9
	Week 8	47	4.34	0.26	3.7	4.1	4.3	4.5	5.0
	Week 12	46	4.33	0.22	3.9	4.2	4.4	4.5	4.8
	End of Treatment	48	4.33	0.22	3.9	4.2	4.4	4.5	4.8
	Follow-up Week 4	48	4.09	0.24	3.7	3.9	4.0	4.3	4.6
	End of Follow-up	48	4.09	0.24	3.7	3.9	4.0	4.3	4.6
Placebo	Screening	41	4.21	0.25	3.7	4.1	4.2	4.3	4.7
	Run-in	41	4.18	0.24	3.6	4.0	4.2	4.3	4.6
	Baseline	41	4.16	0.24	3.8	4.0	4.1	4.3	4.8
	Week 4	40	4.16	0.26	3.5	4.0	4.2	4.3	4.7
	Week 8	39	4.19	0.28	3.5	4.0	4.2	4.4	4.6
	Week 12	40	4.18	0.28	3.6	4.0	4.2	4.4	4.7
	End of Treatment	41	4.19	0.29	3.6	4.0	4.2	4.4	4.7
	Follow-up Week 4	41	4.20	0.27	3.5	4.1	4.2	4.4	4.7
	End of Follow-up	41	4.20	0.27	3.5	4.1	4.2	4.4	4.7

Table 14.3.1-19 Laboratory Tests

Parameter: Aspartate Aminotransferase (U/L)

Group	Time	N	Mean	SD	Min	Q1	Median	Q3	Max
KLH-2109 200 mg	Screening	48	17.8	5.5	12	14	17	20	39
	Run-in	48	16.7	6.2	10	13	15	18	42
	Baseline	48	16.7	5.8	11	13	15	17	40
	Week 4	47	19.9	7.5	12	15	17	20	48
	Week 8	47	21.0	7.2	12	16	19	25	48
	Week 12	46	22.7	9.4	13	16	20	26	55
	End of Treatment	48	22.8	9.3	13	16	20	27	55
	Follow-up Week 4	48	17.9	6.7	11	14	16	21	51
	End of Follow-up	48	17.9	6.7	11	14	16	21	51
Placebo	Screening	41	17.3	5.0	9	14	16	19	36
	Run-in	41	18.0	8.1	10	14	16	19	48
	Baseline	41	18.0	8.8	9	14	16	19	61
	Week 4	40	18.9	8.4	10	15	17	21	59
	Week 8	39	19.4	8.9	11	14	17	23	62
	Week 12	40	19.2	11.1	11	14	16	20	80
	End of Treatment	41	19.0	11.1	11	14	16	20	80
	Follow-up Week 4	41	18.8	13.0	11	14	16	18	96
	End of Follow-up	41	18.8	13.0	11	14	16	18	96

Table 14.3.1-19 Laboratory Tests

Parameter: Alanine Aminotransferase (U/L)

Group	Time	N	Mean	SD	Min	Q1	Median	Q3	Max
KLH-2109 200 mg	Screening	48	14.3	7.8	6	10	12	16	48
	Run-in	48	13.1	9.2	6	8	10	15	58
	Baseline	48	12.9	7.3	5	9	11	14	48
	Week 4	47	19.0	13.7	6	10	15	21	75
	Week 8	47	20.9	14.2	6	12	17	26	81
	Week 12	46	23.9	18.5	7	11	17	26	99
	End of Treatment	48	24.5	18.3	7	12	17	35	99
	Follow-up Week 4	48	15.7	12.0	6	10	13	17	81
	End of Follow-up	48	15.7	12.0	6	10	13	17	81
Placebo	Screening	41	17.3	12.5	7	11	13	19	70
	Run-in	41	17.6	14.0	6	9	13	20	78
	Baseline	41	18.9	17.0	6	10	14	21	94
	Week 4	40	20.1	16.1	6	10	15	25	97
	Week 8	39	20.7	17.4	8	10	15	26	100
	Week 12	40	20.0	20.5	7	10	13	23	122
	End of Treatment	41	19.7	20.3	7	10	13	22	122
	Follow-up Week 4	41	19.6	21.7	6	10	14	19	139
	End of Follow-up	41	19.6	21.7	6	10	14	19	139

Table 14.3.1-19 Laboratory Tests

Parameter: Gamma Glutamyl Transferase (U/L)

Group	Time	N	Mean	SD	Min	Q1	Median	Q3	Max
KLH-2109 200 mg	Screening	48	20.4	17.5	8	11	14	23	100
	Run-in	48	19.3	16.8	8	10	14	22	105
	Baseline	48	19.8	18.4	8	11	15	21	106
	Week 4	47	24.6	24.8	8	12	17	27	139
	Week 8	47	23.6	17.9	9	12	16	28	88
	Week 12	46	23.0	17.8	8	13	16	28	113
	End of Treatment	48	26.2	24.8	8	13	17	32	139
	Follow-up Week 4	48	21.8	20.4	8	10	15	25	118
	End of Follow-up	48	21.8	20.4	8	10	15	25	118
Placebo	Screening	41	23.1	14.4	9	14	18	27	80
	Run-in	41	22.9	15.7	9	13	17	25	87
	Baseline	41	24.5	19.1	10	13	18	28	112
	Week 4	40	28.0	27.7	9	14	17	31	140
	Week 8	39	27.2	27.8	10	14	19	28	155
	Week 12	40	28.2	30.9	9	14	20	29	153
	End of Treatment	41	27.8	30.6	9	14	19	27	153
	Follow-up Week 4	41	27.9	32.9	9	14	17	25	195
	End of Follow-up	41	27.9	32.9	9	14	17	25	195

Table 14.3.1-19 Laboratory Tests

Parameter: Alkaline Phosphatase (U/L)

Group	Time	N	Mean	SD	Min	Q1	Median	Q3	Max
KLH-2109 200 mg	Screening	48	59.7	18.3	33	47	57	68	116
	Run-in	48	59.4	19.1	35	45	57	67	115
	Baseline	48	59.5	19.3	33	45	56	68	114
	Week 4	47	63.2	19.8	37	48	60	69	139
	Week 8	47	63.6	15.9	39	49	61	73	110
	Week 12	46	64.0	14.9	41	53	63	70	108
	End of Treatment	48	66.3	18.8	41	53	63	71	140
	Follow-up Week 4	48	64.9	17.4	40	52	62	70	125
	End of Follow-up	48	64.9	17.4	40	52	62	70	125
Placebo	Screening	41	58.3	16.2	27	48	56	65	99
	Run-in	41	57.9	15.1	25	48	56	66	94
	Baseline	41	58.6	16.3	25	48	58	71	89
	Week 4	40	58.5	17.4	25	49	56	66	98
	Week 8	39	59.3	16.7	26	49	59	69	99
	Week 12	40	60.3	18.4	24	47	57	70	112
	End of Treatment	41	59.9	18.3	24	47	57	70	112
	Follow-up Week 4	41	59.2	18.0	24	47	57	69	95
	End of Follow-up	41	59.2	18.0	24	47	57	69	95

Table 14.3.1-19 Laboratory Tests

Parameter: Creatine Kinase (U/L)

Group	Time	N	Mean	SD	Min	Q1	Median	Q3	Max
KLH-2109 200 mg	Screening	48	75.9	29.3	37	54	72	88	157
	Run-in	48	77.3	29.3	43	61	70	85	190
	Baseline	48	101.0	200.7	33	57	67	92	1455
	Week 4	47	83.3	32.0	41	62	79	95	236
	Week 8	47	80.7	32.0	38	61	70	90	178
	Week 12	46	158.0	525.2	41	62	75	93	3636
	End of Treatment	48	153.8	514.3	41	61	74	93	3636
	Follow-up Week 4	48	144.4	427.7	34	51	62	85	2956
	End of Follow-up	48	144.4	427.7	34	51	62	85	2956
Placebo	Screening	41	76.1	34.7	32	57	70	90	207
	Run-in	41	144.5	408.0	32	57	76	95	2683
	Baseline	41	80.5	34.1	36	54	71	91	196
	Week 4	40	77.0	31.8	33	55	68	95	154
	Week 8	39	74.4	28.2	35	51	71	95	145
	Week 12	40	80.3	42.6	37	54	70	83	204
	End of Treatment	41	80.8	42.2	37	54	73	85	204
	Follow-up Week 4	41	77.4	35.6	30	53	73	92	198
	End of Follow-up	41	77.4	35.6	30	53	73	92	198

Table 14.3.1-19 Laboratory Tests

Parameter: Urate (mg/dL)

Group	Time	N	Mean	SD	Min	Q1	Median	Q3	Max
KLH-2109 200 mg	Screening	48	4.16	0.93	2.2	3.6	4.0	4.6	6.0
	Run-in	48	4.27	1.11	2.0	3.6	4.1	5.0	8.5
	Baseline	48	4.23	0.98	1.9	3.5	4.2	4.9	6.8
	Week 4	47	4.27	1.03	2.2	3.6	4.2	4.9	7.1
	Week 8	47	4.46	1.09	2.1	3.8	4.3	5.2	7.2
	Week 12	46	4.65	1.12	2.4	3.9	4.7	5.3	8.3
	End of Treatment	48	4.66	1.10	2.4	3.9	4.7	5.3	8.3
	Follow-up Week 4	48	4.40	1.20	2.0	3.6	4.4	5.1	8.5
	End of Follow-up	48	4.40	1.20	2.0	3.6	4.4	5.1	8.5
Placebo	Screening	41	4.55	1.20	2.2	3.8	4.4	4.9	7.8
	Run-in	41	4.51	1.12	2.3	3.8	4.4	5.1	7.6
	Baseline	41	4.68	1.03	2.7	4.0	4.6	5.2	7.2
	Week 4	40	4.59	0.93	2.6	3.8	4.5	5.2	7.1
	Week 8	39	4.68	0.95	2.9	4.0	4.5	5.2	7.0
	Week 12	40	4.56	1.05	2.7	3.8	4.4	5.2	7.4
	End of Treatment	41	4.50	1.10	2.3	3.8	4.3	4.9	7.4
	Follow-up Week 4	41	4.54	1.12	2.8	3.7	4.6	4.9	8.8
	End of Follow-up	41	4.54	1.12	2.8	3.7	4.6	4.9	8.8

Table 14.3.1-19 Laboratory Tests

Parameter: Urea Nitrogen (mg/dL)

Group	Time	N	Mean	SD	Min	Q1	Median	Q3	Max
KLH-2109 200 mg	Screening	48	11.62	3.01	5.5	9.2	11.4	13.7	19.7
	Run-in	48	11.61	3.26	6.8	9.1	11.4	13.6	21.1
	Baseline	48	11.42	3.37	6.4	8.7	11.0	13.4	19.7
	Week 4	47	11.85	2.95	7.4	9.5	11.0	13.9	18.9
	Week 8	47	12.39	3.85	6.1	9.4	11.8	14.3	23.4
	Week 12	46	11.98	2.79	8.0	10.2	11.4	13.9	21.5
	End of Treatment	48	11.91	2.75	8.0	10.2	11.2	13.9	21.5
	Follow-up Week 4	48	10.96	3.02	6.6	8.6	10.6	12.6	20.7
	End of Follow-up	48	10.96	3.02	6.6	8.6	10.6	12.6	20.7
Placebo	Screening	41	11.46	2.81	5.6	10.1	10.9	12.8	17.7
	Run-in	41	10.89	2.51	5.5	9.4	10.6	12.4	18.3
	Baseline	41	11.57	2.67	6.3	9.5	11.5	13.4	19.9
	Week 4	40	11.40	2.53	5.0	9.9	11.2	13.1	17.7
	Week 8	39	11.59	2.77	5.9	10.0	11.6	12.7	21.1
	Week 12	40	10.95	3.07	4.9	8.8	11.0	12.7	19.9
	End of Treatment	41	11.01	3.07	4.9	8.9	11.1	12.8	19.9
	Follow-up Week 4	41	11.16	2.48	6.7	10.0	10.8	12.4	17.3
	End of Follow-up	41	11.16	2.48	6.7	10.0	10.8	12.4	17.3

Table 14.3.1-19 Laboratory Tests

Parameter: Lactate Dehydrogenase (U/L)

Group	Time	N	Mean	SD	Min	Q1	Median	Q3	Max
KLH-2109 200 mg	Screening	48	155.3	24.3	100	137	158	167	226
	Run-in	48	158.0	27.0	107	140	157	168	261
	Baseline	48	155.1	25.9	62	137	156	168	224
	Week 4	47	169.2	26.9	116	151	166	181	265
	Week 8	47	167.5	22.8	112	152	168	181	231
	Week 12	46	169.3	23.9	111	156	170	185	244
	End of Treatment	48	168.8	23.5	111	156	170	185	244
	Follow-up Week 4	48	156.4	20.0	114	146	158	169	209
	End of Follow-up	48	156.4	20.0	114	146	158	169	209
Placebo	Screening	41	155.9	24.0	73	144	160	165	197
	Run-in	41	159.7	28.9	90	141	161	176	263
	Baseline	41	158.3	23.9	92	142	154	172	228
	Week 4	40	157.5	22.3	90	145	158	175	202
	Week 8	39	158.2	24.4	77	143	162	175	203
	Week 12	40	159.1	25.6	83	143	159	174	217
	End of Treatment	41	159.0	25.3	83	146	159	173	217
	Follow-up Week 4	41	156.5	25.0	82	144	157	168	208
	End of Follow-up	41	156.5	25.0	82	144	157	168	208

Table 14.3.1-19 Laboratory Tests

Parameter: HDL Cholesterol (mg/dL)

Group	Time	N	Mean	SD	Min	Q1	Median	Q3	Max
KLH-2109 200 mg	Screening	48	65.3	14.2	41	55	63	75	100
	Run-in	48	62.2	12.0	40	56	60	68	91
	Baseline	48	62.7	12.5	41	53	62	70	95
	Week 4	47	65.5	12.7	45	57	64	74	97
	Week 8	47	66.1	13.2	41	55	64	75	100
	Week 12	46	68.3	14.5	41	56	68	78	109
	End of Treatment	48	68.1	14.3	41	58	67	78	109
	Follow-up Week 4	48	64.9	12.4	41	57	66	73	94
	End of Follow-up	48	64.9	12.4	41	57	66	73	94
Placebo	Screening	41	61.5	16.0	28	53	63	71	95
	Run-in	41	59.4	16.3	26	48	59	68	100
	Baseline	41	58.9	15.8	25	48	60	71	95
	Week 4	40	60.8	17.3	30	49	61	74	97
	Week 8	39	60.8	17.4	30	48	60	69	112
	Week 12	40	61.6	17.3	26	51	63	69	104
	End of Treatment	41	61.3	17.2	26	49	62	68	104
	Follow-up Week 4	41	62.0	17.3	31	52	58	78	102
	End of Follow-up	41	62.0	17.3	31	52	58	78	102

Table 14.3.1-19 Laboratory Tests

Parameter: LDL Cholesterol (mg/dL)

Group	Time	N	Mean	SD	Min	Q1	Median	Q3	Max
KLH-2109 200 mg	Screening	48	113.2	23.5	48	99	112	127	193
	Run-in	48	113.0	21.6	56	104	113	124	163
	Baseline	48	112.3	20.6	59	98	113	120	158
	Week 4	47	129.7	24.9	78	112	132	146	202
	Week 8	47	132.5	22.8	82	118	134	144	196
	Week 12	46	130.6	24.1	85	117	130	142	197
	End of Treatment	48	131.5	24.1	85	118	132	143	197
	Follow-up Week 4	48	114.5	23.7	58	102	115	129	188
	End of Follow-up	48	114.5	23.7	58	102	115	129	188
Placebo	Screening	41	128.9	29.7	77	102	137	145	187
	Run-in	41	119.9	28.2	66	98	123	145	182
	Baseline	41	119.2	26.5	72	94	121	138	174
	Week 4	40	118.5	29.9	67	93	123	136	186
	Week 8	39	121.5	30.5	62	94	119	146	191
	Week 12	40	117.9	29.2	74	93	113	140	197
	End of Treatment	41	118.8	29.5	74	94	117	140	197
	Follow-up Week 4	41	122.5	26.6	74	101	122	138	189
	End of Follow-up	41	122.5	26.6	74	101	122	138	189

Table 14.3.1-19 Laboratory Tests

Parameter: Cholesterol (mg/dL)

Group	Time	N	Mean	SD	Min	Q1	Median	Q3	Max
KLH-2109 200 mg	Screening	48	193.7	24.1	141	177	190	210	267
	Run-in	48	190.4	22.6	135	177	187	204	244
	Baseline	48	190.5	22.2	147	177	188	204	251
	Week 4	47	215.8	27.4	151	204	218	235	289
	Week 8	47	219.4	22.3	161	208	220	227	278
	Week 12	46	217.9	25.9	160	202	216	231	293
	End of Treatment	48	218.8	25.9	160	203	218	233	293
	Follow-up Week 4	48	195.8	24.8	149	184	197	211	283
	End of Follow-up	48	195.8	24.8	149	184	197	211	283
Placebo	Screening	41	210.7	30.6	153	190	214	226	284
	Run-in	41	199.4	29.7	138	172	197	217	267
	Baseline	41	197.3	27.1	138	175	201	216	251
	Week 4	40	201.2	31.8	132	180	203	222	262
	Week 8	39	204.8	30.6	143	182	203	229	269
	Week 12	40	200.9	31.3	148	183	193	221	282
	End of Treatment	41	201.6	31.3	148	183	195	224	282
	Follow-up Week 4	41	206.4	28.6	151	190	202	228	277
	End of Follow-up	41	206.4	28.6	151	190	202	228	277

Table 14.3.1-19 Laboratory Tests

Parameter: Triglycerides (mg/dL)

Group	Time	N	Mean	SD	Min	Q1	Median	Q3	Max
KLH-2109 200 mg	Screening	48	84.8	51.5	23	47	66	109	252
	Run-in	48	77.4	38.2	35	49	72	89	221
	Baseline	48	79.9	40.9	24	52	67	111	192
	Week 4	47	104.3	62.5	33	63	83	121	313
	Week 8	47	108.7	72.8	43	65	83	123	366
	Week 12	46	97.2	51.7	34	68	81	105	286
	End of Treatment	48	98.8	52.1	34	68	82	107	286
	Follow-up Week 4	48	81.2	45.1	29	55	72	94	279
	End of Follow-up	48	81.2	45.1	29	55	72	94	279
Placebo	Screening	41	115.3	90.6	32	59	90	136	507
	Run-in	41	109.7	75.1	41	64	86	137	409
	Baseline	41	99.2	71.1	38	52	79	112	429
	Week 4	40	111.8	88.3	31	56	92	127	450
	Week 8	39	120.2	98.1	24	58	90	132	450
	Week 12	40	109.3	92.2	30	58	74	134	544
	End of Treatment	41	108.0	91.4	30	58	73	123	544
	Follow-up Week 4	41	113.7	84.5	39	63	95	129	415
	End of Follow-up	41	113.7	84.5	39	63	95	129	415

Table 14.3.1-19 Laboratory Tests

Parameter: Urinary Specific Gravity

Group	Time	N	Mean	SD	Min	Q1	Median	Q3	Max
KLH-2109 200 mg	Screening	48	1.0180	0.0075	1.005	1.012	1.018	1.024	1.035
	Run-in	47	1.0167	0.0075	1.006	1.010	1.015	1.024	1.035
	Baseline	48	1.0156	0.0084	1.004	1.008	1.014	1.024	1.031
	Week 4	47	1.0146	0.0069	1.003	1.009	1.015	1.019	1.028
	Week 8	47	1.0141	0.0068	1.004	1.009	1.013	1.019	1.031
	Week 12	46	1.0139	0.0066	1.003	1.009	1.012	1.020	1.029
	End of Treatment	48	1.0139	0.0066	1.003	1.009	1.012	1.020	1.029
	Follow-up Week 4	48	1.0157	0.0069	1.004	1.010	1.016	1.021	1.032
	End of Follow-up	48	1.0157	0.0069	1.004	1.010	1.016	1.021	1.032
Placebo	Screening	41	1.0172	0.0085	1.004	1.010	1.016	1.026	1.033
	Run-in	41	1.0168	0.0075	1.003	1.011	1.017	1.023	1.029
	Baseline	41	1.0159	0.0078	1.004	1.008	1.018	1.023	1.027
	Week 4	40	1.0166	0.0082	1.005	1.009	1.016	1.024	1.032
	Week 8	39	1.0161	0.0076	1.004	1.009	1.016	1.021	1.033
	Week 12	40	1.0162	0.0071	1.004	1.011	1.017	1.022	1.034
	End of Treatment	41	1.0163	0.0071	1.004	1.011	1.017	1.022	1.034
	Follow-up Week 4	41	1.0172	0.0076	1.003	1.010	1.019	1.022	1.031
	End of Follow-up	41	1.0172	0.0076	1.003	1.010	1.019	1.022	1.031

Table 14.3.1-19 Laboratory Tests

Parameter: Urinary pH

Group	Time	N	Mean	SD	Min	Q1	Median	Q3	Max
KLH-2109 200 mg	Screening	48	6.28	0.75	5.0	5.5	6.0	7.0	7.5
	Run-in	47	6.26	0.71	5.0	5.5	6.5	6.5	7.5
	Baseline	48	6.38	0.59	5.0	6.0	6.5	7.0	7.5
	Week 4	47	6.32	0.73	5.0	6.0	6.0	7.0	7.5
	Week 8	47	6.41	0.85	5.0	5.5	6.5	7.0	8.0
	Week 12	46	6.22	0.81	5.0	5.5	6.0	7.0	8.0
	End of Treatment	48	6.22	0.80	5.0	5.5	6.0	7.0	8.0
	Follow-up Week 4	48	6.25	0.71	5.0	5.5	6.3	6.8	7.5
	End of Follow-up	48	6.25	0.71	5.0	5.5	6.3	6.8	7.5
Placebo	Screening	41	6.06	0.70	5.0	5.5	6.0	6.5	8.0
	Run-in	41	6.11	0.65	5.0	5.5	6.0	6.5	7.5
	Baseline	41	6.13	0.64	5.0	5.5	6.0	6.5	7.5
	Week 4	40	6.03	0.76	5.0	5.5	6.0	6.5	7.5
	Week 8	39	6.14	0.73	5.0	5.5	6.0	6.5	8.0
	Week 12	40	6.19	0.72	5.0	5.5	6.0	6.5	7.5
	End of Treatment	41	6.20	0.71	5.0	5.5	6.0	6.5	7.5
	Follow-up Week 4	41	6.11	0.72	5.0	5.5	6.0	6.5	8.0
	End of Follow-up	41	6.11	0.72	5.0	5.5	6.0	6.5	8.0

Table 14.3.1-20 Change from Baseline in Laboratory Tests

Parameter: Erythrocytes (10^4/uL)

Group	Time	N	Mean	SD	Min	Q1	Median	Q3	Max
KLH-2109 200 mg	Week 4	47	26.8	22.2	-15	14	30	42	78
	Week 8	47	30.4	26.0	-12	9	29	48	90
	Week 12	46	33.0	28.8	-40	15	32	49	107
	End of Treatment	48	32.3	28.4	-40	14	30	49	107
	Follow-up Week 4	48	7.6	24.9	-48	-6	10	26	61
	End of Follow-up	48	7.6	24.9	-48	-6	10	26	61
Placebo	Week 4	40	-0.4	20.5	-72	-9	-2	11	45
	Week 8	39	8.9	25.0	-41	-10	15	31	56
	Week 12	40	2.2	31.8	-53	-18	-3	17	77
	End of Treatment	41	2.0	31.4	-53	-18	-3	15	77
	Follow-up Week 4	41	5.2	32.6	-73	-15	-2	22	103
	End of Follow-up	41	5.2	32.6	-73	-15	-2	22	103

Table 14.3.1-20 Change from Baseline in Laboratory Tests

Parameter: Leukocytes (/uL)

Group	Time	N	Mean	SD	Min	Q1	Median	Q3	Max
KLH-2109 200 mg	Week 4	47	-70	1080	-3500	-500	0	500	2300
	Week 8	47	-230	1160	-3700	-900	-200	600	2400
	Week 12	46	-270	1070	-2800	-900	-200	400	2300
	End of Treatment	48	-310	1060	-2800	-1000	-200	400	2300
	Follow-up Week 4	48	430	1260	-3200	-400	500	1100	4100
	End of Follow-up	48	430	1260	-3200	-400	500	1100	4100
Placebo	Week 4	40	470	1220	-2500	-400	400	1400	2900
	Week 8	39	750	1190	-1500	100	500	1200	4700
	Week 12	40	550	1100	-1500	-300	400	1100	3700
	End of Treatment	41	570	1090	-1500	-200	400	1100	3700
	Follow-up Week 4	41	690	1250	-1400	-100	500	1100	4700
	End of Follow-up	41	690	1250	-1400	-100	500	1100	4700

Table 14.3.1-20 Change from Baseline in Laboratory Tests

Parameter: Platelets (10^4/uL)

Group	Time	N	Mean	SD	Min	Q1	Median	Q3	Max
KLH-2109 200 mg	Week 4	46	-1.34	3.96	-10.0	-3.8	-0.7	0.6	15.4
	Week 8	47	-0.36	3.88	-7.6	-2.6	-0.7	1.8	15.2
	Week 12	46	-1.13	3.08	-9.1	-3.3	-0.4	0.5	5.7
	End of Treatment	48	-1.14	3.02	-9.1	-3.2	-0.4	0.5	5.7
	Follow-up Week 4	48	0.04	3.57	-8.1	-1.8	0.3	1.8	9.2
	End of Follow-up	48	0.04	3.57	-8.1	-1.8	0.3	1.8	9.2
Placebo	Week 4	40	0.51	2.49	-4.3	-0.7	0.3	1.8	8.9
	Week 8	39	0.36	2.22	-5.1	-0.9	0.1	1.8	5.0
	Week 12	40	1.16	3.50	-3.4	-1.4	0.3	2.1	11.3
	End of Treatment	41	1.16	3.45	-3.4	-1.2	0.4	2.0	11.3
	Follow-up Week 4	41	1.11	3.37	-6.4	-0.8	0.9	2.0	12.8
	End of Follow-up	41	1.11	3.37	-6.4	-0.8	0.9	2.0	12.8

Table 14.3.1-20 Change from Baseline in Laboratory Tests

Parameter: Activated Partial Thromboplastin Time (sec)

Group	Time	N	Mean	SD	Min	Q1	Median	Q3	Max
KLH-2109 200 mg	Week 4	47	1.17	3.21	-7.4	-0.2	0.8	1.7	17.1
	Week 8	47	1.50	2.06	-2.2	-0.3	1.3	3.2	6.5
	Week 12	46	1.94	1.93	-2.6	0.5	1.6	3.3	6.2
	End of Treatment	48	1.91	1.92	-2.6	0.5	1.6	3.3	6.2
	Follow-up Week 4	48	1.03	2.36	-4.7	-0.3	1.0	2.3	6.0
	End of Follow-up	48	1.03	2.36	-4.7	-0.3	1.0	2.3	6.0
Placebo	Week 4	40	0.18	2.99	-8.1	-1.1	-0.4	0.9	11.2
	Week 8	39	0.31	3.22	-10.6	-1.1	0.1	2.0	9.0
	Week 12	40	0.59	2.90	-8.9	-1.3	0.2	1.8	7.4
	End of Treatment	41	0.59	2.86	-8.9	-1.2	0.2	1.7	7.4
	Follow-up Week 4	41	0.60	3.09	-11.4	-1.0	0.2	2.5	6.8
	End of Follow-up	41	0.60	3.09	-11.4	-1.0	0.2	2.5	6.8

Table 14.3.1-20 Change from Baseline in Laboratory Tests

Parameter: Prothrombin Time (sec)

Group	Time	N	Mean	SD	Min	Q1	Median	Q3	Max
KLH-2109 200 mg	Week 4	47	0.13	0.69	-1.1	-0.3	0.0	0.7	1.6
	Week 8	47	0.04	0.69	-1.5	-0.4	0.1	0.6	1.4
	Week 12	46	0.12	0.60	-1.3	-0.3	0.2	0.6	1.3
	End of Treatment	48	0.13	0.59	-1.3	-0.3	0.2	0.6	1.3
	Follow-up Week 4	48	0.35	0.69	-1.2	-0.2	0.5	0.9	1.7
	End of Follow-up	48	0.35	0.69	-1.2	-0.2	0.5	0.9	1.7
Placebo	Week 4	40	0.06	0.57	-1.2	-0.3	0.1	0.5	1.1
	Week 8	39	0.16	0.50	-1.4	-0.1	0.2	0.5	1.1
	Week 12	40	0.36	0.54	-1.1	-0.1	0.4	0.7	1.5
	End of Treatment	41	0.34	0.55	-1.1	-0.1	0.4	0.7	1.5
	Follow-up Week 4	41	0.28	0.51	-1.0	0.1	0.4	0.6	1.6
	End of Follow-up	41	0.28	0.51	-1.0	0.1	0.4	0.6	1.6

Table 14.3.1-20 Change from Baseline in Laboratory Tests

Parameter: Prothrombin Intl. Normalized Ratio

Group	Time	N	Mean	SD	Min	Q1	Median	Q3	Max
KLH-2109 200 mg	Week 4	47	0.004	0.055	-0.10	-0.03	0.00	0.06	0.11
	Week 8	47	-0.008	0.058	-0.13	-0.04	-0.01	0.03	0.12
	Week 12	46	-0.001	0.050	-0.11	-0.04	0.00	0.03	0.11
	End of Treatment	48	-0.001	0.049	-0.11	-0.04	0.00	0.03	0.11
	Follow-up Week 4	48	0.013	0.065	-0.14	-0.04	0.03	0.07	0.11
	End of Follow-up	48	0.013	0.065	-0.14	-0.04	0.03	0.07	0.11
Placebo	Week 4	40	-0.001	0.048	-0.11	-0.03	0.01	0.04	0.10
	Week 8	39	0.003	0.041	-0.12	-0.02	0.00	0.03	0.09
	Week 12	40	0.015	0.046	-0.10	-0.01	0.00	0.05	0.12
	End of Treatment	41	0.014	0.046	-0.10	-0.01	0.00	0.04	0.12
	Follow-up Week 4	41	0.007	0.042	-0.09	-0.02	0.01	0.03	0.10
	End of Follow-up	41	0.007	0.042	-0.09	-0.02	0.01	0.03	0.10

Table 14.3.1-20 Change from Baseline in Laboratory Tests

Parameter: Sodium (mEq/L)

Group	Time	N	Mean	SD	Min	Q1	Median	Q3	Max
KLH-2109 200 mg	Week 4	47	0.5	1.7	-5	0	1	2	3
	Week 8	47	0.7	1.7	-3	-1	1	1	5
	Week 12	46	1.1	1.8	-3	0	1	2	6
	End of Treatment	48	1.0	1.8	-3	0	1	2	6
	Follow-up Week 4	48	-0.5	2.0	-6	-1	0	1	2
	End of Follow-up	48	-0.5	2.0	-6	-1	0	1	2
Placebo	Week 4	40	0.0	1.6	-3	-1	0	1	4
	Week 8	39	-0.5	1.7	-4	-2	-1	0	4
	Week 12	40	-0.7	1.9	-4	-2	-1	1	4
	End of Treatment	41	-0.7	1.9	-4	-2	-1	1	4
	Follow-up Week 4	41	-0.4	1.6	-4	-1	-1	1	3
	End of Follow-up	41	-0.4	1.6	-4	-1	-1	1	3

Table 14.3.1-20 Change from Baseline in Laboratory Tests

Parameter: Potassium (mEq/L)

Group	Time	N	Mean	SD	Min	Q1	Median	Q3	Max
KLH-2109 200 mg	Week 4	47	0.00	0.31	-0.8	-0.2	0.0	0.2	0.8
	Week 8	47	0.02	0.22	-0.5	-0.1	0.0	0.2	0.5
	Week 12	46	0.03	0.24	-0.4	-0.1	0.0	0.2	0.5
	End of Treatment	48	0.03	0.24	-0.4	-0.1	0.0	0.2	0.5
	Follow-up Week 4	48	0.04	0.27	-0.4	-0.1	0.0	0.2	1.2
	End of Follow-up	48	0.04	0.27	-0.4	-0.1	0.0	0.2	1.2
Placebo	Week 4	40	0.00	0.29	-0.5	-0.2	0.0	0.2	0.7
	Week 8	39	-0.02	0.31	-0.6	-0.2	0.0	0.2	1.0
	Week 12	40	-0.02	0.24	-0.6	-0.2	0.0	0.1	0.5
	End of Treatment	41	-0.01	0.24	-0.6	-0.1	0.0	0.1	0.5
	Follow-up Week 4	41	0.01	0.33	-0.7	-0.2	-0.1	0.2	1.0
	End of Follow-up	41	0.01	0.33	-0.7	-0.2	-0.1	0.2	1.0

Table 14.3.1-20 Change from Baseline in Laboratory Tests

Parameter: Calcium (mg/dL)

Group	Time	N	Mean	SD	Min	Q1	Median	Q3	Max
KLH-2109 200 mg	Week 4	47	0.35	0.29	-0.6	0.1	0.4	0.5	1.0
	Week 8	47	0.53	0.23	0.2	0.4	0.5	0.7	1.1
	Week 12	46	0.53	0.27	0.0	0.3	0.5	0.7	1.1
	End of Treatment	48	0.52	0.26	0.0	0.3	0.5	0.7	1.1
	Follow-up Week 4	48	0.07	0.27	-0.6	-0.1	0.1	0.2	0.8
	End of Follow-up	48	0.07	0.27	-0.6	-0.1	0.1	0.2	0.8
Placebo	Week 4	40	0.01	0.28	-0.5	-0.2	0.0	0.2	0.6
	Week 8	39	0.08	0.31	-0.4	-0.2	0.0	0.4	0.9
	Week 12	40	0.06	0.34	-0.8	-0.2	0.1	0.3	0.7
	End of Treatment	41	0.06	0.33	-0.8	-0.2	0.1	0.3	0.7
	Follow-up Week 4	41	0.11	0.34	-0.7	-0.1	0.1	0.4	0.8
	End of Follow-up	41	0.11	0.34	-0.7	-0.1	0.1	0.4	0.8

Table 14.3.1-20 Change from Baseline in Laboratory Tests

Parameter: Phosphate (mg/dL)

Group	Time	N	Mean	SD	Min	Q1	Median	Q3	Max
KLH-2109 200 mg	Week 4	47	0.29	0.49	-1.0	-0.1	0.3	0.6	1.2
	Week 8	47	0.45	0.42	-0.5	0.2	0.4	0.8	1.4
	Week 12	46	0.56	0.48	-0.5	0.2	0.6	0.9	1.6
	End of Treatment	48	0.54	0.49	-0.5	0.2	0.6	0.9	1.6
	Follow-up Week 4	48	0.10	0.46	-0.9	-0.2	0.1	0.4	1.2
	End of Follow-up	48	0.10	0.46	-0.9	-0.2	0.1	0.4	1.2
Placebo	Week 4	40	-0.08	0.44	-1.0	-0.4	-0.1	0.3	0.7
	Week 8	39	0.08	0.43	-0.7	-0.2	0.1	0.3	1.0
	Week 12	40	-0.05	0.52	-1.1	-0.4	-0.1	0.3	0.9
	End of Treatment	41	-0.05	0.51	-1.1	-0.4	-0.1	0.3	0.9
	Follow-up Week 4	41	-0.02	0.46	-0.8	-0.4	-0.1	0.4	1.2
	End of Follow-up	41	-0.02	0.46	-0.8	-0.4	-0.1	0.4	1.2

Table 14.3.1-20 Change from Baseline in Laboratory Tests

Parameter: Creatinine (mg/dL)

Group	Time	N	Mean	SD	Min	Q1	Median	Q3	Max
KLH-2109 200 mg	Week 4	47	0.055	0.066	-0.10	0.02	0.04	0.09	0.29
	Week 8	47	0.052	0.058	-0.07	0.02	0.05	0.08	0.19
	Week 12	46	0.060	0.054	-0.09	0.03	0.06	0.09	0.20
	End of Treatment	48	0.056	0.055	-0.09	0.03	0.06	0.09	0.20
	Follow-up Week 4	48	-0.014	0.053	-0.21	-0.04	-0.01	0.01	0.12
	End of Follow-up	48	-0.014	0.053	-0.21	-0.04	-0.01	0.01	0.12
Placebo	Week 4	40	-0.007	0.051	-0.11	-0.05	-0.01	0.03	0.12
	Week 8	39	-0.002	0.041	-0.08	-0.03	-0.01	0.02	0.09
	Week 12	40	-0.002	0.046	-0.11	-0.03	0.00	0.03	0.10
	End of Treatment	41	-0.002	0.045	-0.11	-0.03	0.00	0.03	0.10
	Follow-up Week 4	41	0.001	0.067	-0.12	-0.05	-0.01	0.06	0.13
	End of Follow-up	41	0.001	0.067	-0.12	-0.05	-0.01	0.06	0.13

Table 14.3.1-20 Change from Baseline in Laboratory Tests

Parameter: Bilirubin (mg/dL)

Group	Time	N	Mean	SD	Min	Q1	Median	Q3	Max
KLH-2109 200 mg	Week 4	47	0.04	0.14	-0.3	0.0	0.0	0.1	0.4
	Week 8	47	0.07	0.20	-0.3	-0.1	0.0	0.2	0.9
	Week 12	46	0.12	0.17	-0.2	0.0	0.1	0.2	0.6
	End of Treatment	48	0.12	0.17	-0.2	0.0	0.1	0.2	0.6
	Follow-up Week 4	48	0.13	0.23	-0.2	-0.1	0.1	0.3	0.9
	End of Follow-up	48	0.13	0.23	-0.2	-0.1	0.1	0.3	0.9
Placebo	Week 4	40	0.03	0.13	-0.3	-0.1	0.0	0.1	0.3
	Week 8	39	0.05	0.15	-0.4	0.0	0.1	0.1	0.3
	Week 12	40	0.07	0.17	-0.3	0.0	0.1	0.2	0.4
	End of Treatment	41	0.06	0.17	-0.3	0.0	0.1	0.2	0.4
	Follow-up Week 4	41	0.05	0.21	-0.3	-0.1	0.0	0.1	0.5
	End of Follow-up	41	0.05	0.21	-0.3	-0.1	0.0	0.1	0.5

Table 14.3.1-20 Change from Baseline in Laboratory Tests

Parameter: Protein (g/dL)

Group	Time	N	Mean	SD	Min	Q1	Median	Q3	Max
KLH-2109 200 mg	Week 4	47	0.35	0.32	-0.6	0.2	0.4	0.5	1.0
	Week 8	47	0.42	0.31	-0.1	0.2	0.4	0.6	1.3
	Week 12	46	0.40	0.29	-0.3	0.2	0.4	0.6	1.3
	End of Treatment	48	0.40	0.29	-0.3	0.2	0.4	0.6	1.3
	Follow-up Week 4	48	0.01	0.29	-0.6	-0.2	0.0	0.3	0.7
	End of Follow-up	48	0.01	0.29	-0.6	-0.2	0.0	0.3	0.7
Placebo	Week 4	40	0.01	0.31	-1.0	-0.1	0.0	0.2	0.5
	Week 8	39	0.08	0.33	-0.8	-0.1	0.1	0.3	0.7
	Week 12	40	0.04	0.31	-0.7	-0.2	0.0	0.3	0.6
	End of Treatment	41	0.04	0.30	-0.7	-0.1	0.0	0.3	0.6
	Follow-up Week 4	41	0.09	0.29	-0.8	0.0	0.1	0.2	0.5
	End of Follow-up	41	0.09	0.29	-0.8	0.0	0.1	0.2	0.5

Table 14.3.1-20 Change from Baseline in Laboratory Tests

Parameter: Albumin (g/dL)

Group	Time	N	Mean	SD	Min	Q1	Median	Q3	Max
KLH-2109 200 mg	Week 4	47	0.19	0.20	-0.3	0.0	0.2	0.3	0.6
	Week 8	47	0.22	0.22	-0.4	0.1	0.2	0.4	0.7
	Week 12	46	0.22	0.19	-0.2	0.1	0.2	0.4	0.7
	End of Treatment	48	0.22	0.19	-0.2	0.1	0.2	0.4	0.7
	Follow-up Week 4	48	-0.03	0.20	-0.5	-0.1	0.0	0.1	0.4
	End of Follow-up	48	-0.03	0.20	-0.5	-0.1	0.0	0.1	0.4
Placebo	Week 4	40	0.00	0.23	-0.6	-0.1	0.0	0.1	0.4
	Week 8	39	0.04	0.24	-0.6	-0.1	0.0	0.2	0.5
	Week 12	40	0.02	0.25	-0.5	-0.2	0.0	0.2	0.5
	End of Treatment	41	0.02	0.25	-0.5	-0.2	0.0	0.2	0.5
	Follow-up Week 4	41	0.03	0.20	-0.5	-0.1	0.1	0.1	0.4
	End of Follow-up	41	0.03	0.20	-0.5	-0.1	0.1	0.1	0.4

Table 14.3.1-20 Change from Baseline in Laboratory Tests

Parameter: Aspartate Aminotransferase (U/L)

Group	Time	N	Mean	SD	Min	Q1	Median	Q3	Max
KLH-2109 200 mg	Week 4	47	3.3	5.8	-12	0	3	5	24
	Week 8	47	4.7	6.2	-19	2	4	8	19
	Week 12	46	6.5	8.3	-8	2	4	9	36
	End of Treatment	48	6.1	8.6	-12	2	4	9	36
	Follow-up Week 4	48	1.3	6.0	-17	-2	1	3	20
	End of Follow-up	48	1.3	6.0	-17	-2	1	3	20
Placebo	Week 4	40	0.8	3.3	-7	-1	1	2	8
	Week 8	39	1.2	3.9	-11	-1	1	4	11
	Week 12	40	1.1	6.1	-18	-1	1	4	20
	End of Treatment	41	1.0	6.1	-18	-1	0	4	20
	Follow-up Week 4	41	0.8	7.0	-17	-2	1	2	35
	End of Follow-up	41	0.8	7.0	-17	-2	1	2	35

Table 14.3.1-20 Change from Baseline in Laboratory Tests

Parameter: Alanine Aminotransferase (U/L)

Group	Time	N	Mean	SD	Min	Q1	Median	Q3	Max
KLH-2109 200 mg	Week 4	47	6.1	8.7	-4	1	4	8	36
	Week 8	47	8.4	9.6	-9	1	5	15	34
	Week 12	46	11.6	14.4	-5	1	6	16	51
	End of Treatment	48	11.6	14.2	-5	2	6	17	51
	Follow-up Week 4	48	2.8	7.2	-7	-2	2	5	33
	End of Follow-up	48	2.8	7.2	-7	-2	2	5	33
Placebo	Week 4	40	0.9	6.3	-30	-1	1	3	12
	Week 8	39	1.2	6.7	-25	-2	1	3	17
	Week 12	40	0.8	11.6	-38	-2	0	3	44
	End of Treatment	41	0.8	11.5	-38	-2	0	3	44
	Follow-up Week 4	41	0.7	11.5	-38	-3	1	3	45
	End of Follow-up	41	0.7	11.5	-38	-3	1	3	45

Table 14.3.1-20 Change from Baseline in Laboratory Tests

Parameter: Gamma Glutamyl Transferase (U/L)

Group	Time	N	Mean	SD	Min	Q1	Median	Q3	Max
KLH-2109 200 mg	Week 4	47	4.6	8.5	-10	1	2	6	37
	Week 8	47	5.7	9.3	-8	1	2	7	43
	Week 12	46	5.4	7.1	-5	2	3	10	28
	End of Treatment	48	6.4	8.6	-5	2	3	11	33
	Follow-up Week 4	48	2.1	5.2	-10	-1	1	3	23
	End of Follow-up	48	2.1	5.2	-10	-1	1	3	23
Placebo	Week 4	40	3.3	12.1	-7	-1	0	3	56
	Week 8	39	2.3	11.2	-10	-1	1	2	49
	Week 12	40	3.4	15.0	-12	-2	0	4	82
	End of Treatment	41	3.3	14.8	-12	-1	0	4	82
	Follow-up Week 4	41	3.4	16.3	-23	-1	0	2	83
	End of Follow-up	41	3.4	16.3	-23	-1	0	2	83

Table 14.3.1-20 Change from Baseline in Laboratory Tests

Parameter: Alkaline Phosphatase (U/L)

Group	Time	N	Mean	SD	Min	Q1	Median	Q3	Max
KLH-2109 200 mg	Week 4	47	3.9	7.1	-9	-1	4	8	25
	Week 8	47	5.2	7.3	-14	2	6	10	22
	Week 12	46	6.7	7.3	-12	2	9	12	20
	End of Treatment	48	6.8	8.0	-12	2	9	12	26
	Follow-up Week 4	48	5.4	8.7	-15	-2	7	11	22
	End of Follow-up	48	5.4	8.7	-15	-2	7	11	22
Placebo	Week 4	40	-0.5	6.0	-16	-4	-1	2	17
	Week 8	39	0.4	6.0	-12	-3	0	3	19
	Week 12	40	1.3	8.0	-12	-4	0	5	32
	End of Treatment	41	1.3	7.9	-12	-4	0	5	32
	Follow-up Week 4	41	0.5	6.2	-12	-3	0	4	14
	End of Follow-up	41	0.5	6.2	-12	-3	0	4	14

Table 14.3.1-20 Change from Baseline in Laboratory Tests

Parameter: Creatine Kinase (U/L)

Group	Time	N	Mean	SD	Min	Q1	Median	Q3	Max
KLH-2109 200 mg	Week 4	47	-17.9	200.0	-1348	-2	6	17	142
	Week 8	47	-21.2	200.5	-1355	-8	4	16	98
	Week 12	46	55.0	561.0	-1222	-10	3	14	3576
	End of Treatment	48	52.7	549.1	-1222	-10	3	14	3576
	Follow-up Week 4	48	43.3	477.9	-1385	-17	-7	5	2896
	End of Follow-up	48	43.3	477.9	-1385	-17	-7	5	2896
Placebo	Week 4	40	-2.3	29.7	-137	-11	-3	7	58
	Week 8	39	-5.1	17.8	-51	-16	-4	4	45
	Week 12	40	1.1	38.3	-132	-13	-5	9	148
	End of Treatment	41	0.2	38.2	-132	-14	-5	8	148
	Follow-up Week 4	41	-3.1	28.0	-121	-13	-2	9	52
	End of Follow-up	41	-3.1	28.0	-121	-13	-2	9	52

Table 14.3.1-20 Change from Baseline in Laboratory Tests

Parameter: Urate (mg/dL)

Group	Time	N	Mean	SD	Min	Q1	Median	Q3	Max
KLH-2109 200 mg	Week 4	47	0.04	0.47	-1.1	-0.2	-0.1	0.3	1.2
	Week 8	47	0.23	0.54	-0.8	-0.2	0.3	0.6	1.5
	Week 12	46	0.44	0.64	-1.0	0.0	0.5	0.8	1.8
	End of Treatment	48	0.43	0.62	-1.0	0.1	0.5	0.8	1.8
	Follow-up Week 4	48	0.17	0.58	-0.9	-0.2	0.1	0.6	1.7
	End of Follow-up	48	0.17	0.58	-0.9	-0.2	0.1	0.6	1.7
Placebo	Week 4	40	-0.14	0.60	-1.6	-0.5	-0.2	0.1	1.2
	Week 8	39	-0.05	0.45	-1.1	-0.3	0.0	0.2	1.1
	Week 12	40	-0.18	0.48	-1.2	-0.6	-0.2	0.2	1.0
	End of Treatment	41	-0.18	0.48	-1.2	-0.5	-0.2	0.1	1.0
	Follow-up Week 4	41	-0.14	0.66	-1.9	-0.5	-0.1	0.2	1.8
	End of Follow-up	41	-0.14	0.66	-1.9	-0.5	-0.1	0.2	1.8

Table 14.3.1-20 Change from Baseline in Laboratory Tests

Parameter: Urea Nitrogen (mg/dL)

Group	Time	N	Mean	SD	Min	Q1	Median	Q3	Max
KLH-2109 200 mg	Week 4	47	0.54	2.58	-5.1	-1.1	1.0	2.6	5.2
	Week 8	47	1.05	3.70	-7.0	-0.8	0.7	2.4	14.0
	Week 12	46	0.58	2.33	-5.1	-0.6	0.9	2.2	4.5
	End of Treatment	48	0.50	2.41	-5.1	-0.7	0.9	2.1	4.5
	Follow-up Week 4	48	-0.46	3.14	-9.5	-2.0	-0.5	1.4	5.9
	End of Follow-up	48	-0.46	3.14	-9.5	-2.0	-0.5	1.4	5.9
Placebo	Week 4	40	-0.30	2.84	-4.7	-2.8	-0.7	1.9	6.9
	Week 8	39	-0.10	3.15	-7.5	-2.1	-0.4	2.2	7.7
	Week 12	40	-0.75	2.39	-5.5	-2.6	-0.9	0.6	6.5
	End of Treatment	41	-0.55	2.69	-5.5	-2.6	-0.8	0.6	7.5
	Follow-up Week 4	41	-0.40	3.09	-8.7	-1.7	0.4	1.4	5.9
	End of Follow-up	41	-0.40	3.09	-8.7	-1.7	0.4	1.4	5.9

Table 14.3.1-20 Change from Baseline in Laboratory Tests

Parameter: Lactate Dehydrogenase (U/L)

Group	Time	N	Mean	SD	Min	Q1	Median	Q3	Max
KLH-2109 200 mg	Week 4	47	14.4	24.7	-37	-1	12	21	99
	Week 8	47	12.7	21.2	-40	2	12	22	79
	Week 12	46	14.4	22.1	-48	2	10	24	78
	End of Treatment	48	13.7	22.0	-48	2	10	23	78
	Follow-up Week 4	48	1.3	20.1	-58	-7	-1	11	54
	End of Follow-up	48	1.3	20.1	-58	-7	-1	11	54
Placebo	Week 4	40	-0.4	13.0	-46	-8	-2	8	20
	Week 8	39	0.9	14.8	-31	-9	4	13	25
	Week 12	40	1.3	14.3	-29	-10	1	12	41
	End of Treatment	41	0.7	14.5	-29	-11	1	12	41
	Follow-up Week 4	41	-1.8	12.9	-32	-10	-1	6	32
	End of Follow-up	41	-1.8	12.9	-32	-10	-1	6	32

Table 14.3.1-20 Change from Baseline in Laboratory Tests

Parameter: HDL Cholesterol (mg/dL)

Group	Time	N	Mean	SD	Min	Q1	Median	Q3	Max
KLH-2109 200 mg	Week 4	47	2.6	8.1	-29	-1	4	7	19
	Week 8	47	3.4	9.6	-26	0	5	8	24
	Week 12	46	5.6	7.9	-16	0	6	11	24
	End of Treatment	48	5.4	7.8	-16	1	5	11	24
	Follow-up Week 4	48	2.3	7.5	-20	-2	2	7	21
	End of Follow-up	48	2.3	7.5	-20	-2	2	7	21
Placebo	Week 4	40	1.7	5.9	-11	-2	2	5	15
	Week 8	39	2.1	7.3	-16	-1	1	5	26
	Week 12	40	2.5	6.9	-17	0	3	8	19
	End of Treatment	41	2.4	6.9	-17	0	3	7	19
	Follow-up Week 4	41	3.1	8.5	-19	-2	2	7	23
	End of Follow-up	41	3.1	8.5	-19	-2	2	7	23

Table 14.3.1-20 Change from Baseline in Laboratory Tests

Parameter: LDL Cholesterol (mg/dL)

Group	Time	N	Mean	SD	Min	Q1	Median	Q3	Max
KLH-2109 200 mg	Week 4	47	17.3	19.0	-19	1	17	34	58
	Week 8	47	21.1	16.3	-10	8	20	34	56
	Week 12	46	19.9	13.7	-10	10	20	31	50
	End of Treatment	48	19.2	14.3	-14	10	20	31	50
	Follow-up Week 4	48	2.3	17.1	-41	-7	7	14	35
	End of Follow-up	48	2.3	17.1	-41	-7	7	14	35
Placebo	Week 4	40	-0.1	12.0	-30	-7	-1	8	31
	Week 8	39	2.8	18.8	-47	-7	4	17	49
	Week 12	40	-0.7	16.8	-34	-11	-2	10	41
	End of Treatment	41	-0.4	16.7	-34	-10	-2	10	41
	Follow-up Week 4	41	3.2	16.6	-33	-8	3	14	45
	End of Follow-up	41	3.2	16.6	-33	-8	3	14	45

Table 14.3.1-20 Change from Baseline in Laboratory Tests

Parameter: Cholesterol (mg/dL)

Group	Time	N	Mean	SD	Min	Q1	Median	Q3	Max
KLH-2109 200 mg	Week 4	47	25.0	22.0	-25	13	22	46	64
	Week 8	47	29.7	18.5	-1	13	26	49	66
	Week 12	46	29.0	17.1	-15	16	31	41	65
	End of Treatment	48	28.3	17.4	-15	15	30	41	65
	Follow-up Week 4	48	5.2	19.4	-47	-8	7	20	43
	End of Follow-up	48	5.2	19.4	-47	-8	7	20	43
Placebo	Week 4	40	4.4	14.8	-22	-6	3	12	34
	Week 8	39	8.3	20.5	-42	-5	8	24	65
	Week 12	40	4.1	19.6	-30	-10	2	18	55
	End of Treatment	41	4.3	19.4	-30	-9	2	17	55
	Follow-up Week 4	41	9.1	19.0	-30	-6	9	21	64
	End of Follow-up	41	9.1	19.0	-30	-6	9	21	64

Table 14.3.1-20 Change from Baseline in Laboratory Tests

Parameter: Triglycerides (mg/dL)

Group	Time	N	Mean	SD	Min	Q1	Median	Q3	Max
KLH-2109 200 mg	Week 4	47	25.5	48.4	-87	2	19	44	194
	Week 8	47	28.2	55.3	-75	6	20	39	224
	Week 12	46	18.5	38.7	-63	-8	13	43	112
	End of Treatment	48	18.8	38.0	-63	-8	14	40	112
	Follow-up Week 4	48	1.3	34.9	-68	-19	2	16	171
	End of Follow-up	48	1.3	34.9	-68	-19	2	16	171
Placebo	Week 4	40	11.7	42.8	-53	-11	3	19	169
	Week 8	39	20.4	69.2	-77	-8	4	21	314
	Week 12	40	9.3	40.2	-97	-14	3	23	115
	End of Treatment	41	8.8	39.8	-97	-13	3	19	115
	Follow-up Week 4	41	14.5	57.9	-75	-5	1	24	237
	End of Follow-up	41	14.5	57.9	-75	-5	1	24	237

Table 14.3.1-20 Change from Baseline in Laboratory Tests

Parameter: Urinary Specific Gravity

Group	Time	N	Mean	SD	Min	Q1	Median	Q3	Max
KLH-2109 200 mg	Week 4	47	-0.0008	0.0074	-0.016	-0.005	-0.001	0.004	0.012
	Week 8	47	-0.0011	0.0069	-0.014	-0.007	-0.001	0.003	0.015
	Week 12	46	-0.0015	0.0090	-0.020	-0.007	-0.001	0.005	0.020
	End of Treatment	48	-0.0017	0.0089	-0.020	-0.008	-0.001	0.005	0.020
	Follow-up Week 4	48	0.0001	0.0091	-0.020	-0.006	0.000	0.005	0.022
	End of Follow-up	48	0.0001	0.0091	-0.020	-0.006	0.000	0.005	0.022
Placebo	Week 4	40	0.0006	0.0092	-0.020	-0.005	0.000	0.007	0.020
	Week 8	39	-0.0003	0.0101	-0.018	-0.007	0.000	0.005	0.025
	Week 12	40	0.0002	0.0085	-0.018	-0.004	0.001	0.005	0.017
	End of Treatment	41	0.0005	0.0086	-0.018	-0.004	0.001	0.005	0.017
	Follow-up Week 4	41	0.0014	0.0100	-0.023	-0.004	0.002	0.009	0.017
	End of Follow-up	41	0.0014	0.0100	-0.023	-0.004	0.002	0.009	0.017

Table 14.3.1-20 Change from Baseline in Laboratory Tests

Parameter: Urinary pH

Group	Time	N	Mean	SD	Min	Q1	Median	Q3	Max
KLH-2109 200 mg	Week 4	47	-0.04	0.73	-2.0	-0.5	0.0	0.5	1.5
	Week 8	47	0.03	0.78	-1.5	-0.5	0.0	0.5	2.0
	Week 12	46	-0.16	0.75	-1.5	-0.5	0.0	0.5	1.5
	End of Treatment	48	-0.16	0.74	-1.5	-0.5	0.0	0.5	1.5
	Follow-up Week 4	48	-0.13	0.74	-1.5	-0.5	0.0	0.5	1.5
	End of Follow-up	48	-0.13	0.74	-1.5	-0.5	0.0	0.5	1.5
Placebo	Week 4	40	-0.13	0.91	-2.0	-1.0	0.0	0.5	2.0
	Week 8	39	0.00	0.73	-1.5	-0.5	0.0	0.5	2.0
	Week 12	40	0.04	0.75	-2.0	-0.5	0.0	0.5	1.5
	End of Treatment	41	0.06	0.75	-2.0	-0.5	0.0	0.5	1.5
	Follow-up Week 4	41	-0.02	0.92	-2.0	-0.5	0.0	0.5	2.5
	End of Follow-up	41	-0.02	0.92	-2.0	-0.5	0.0	0.5	2.5

Table 14.3.1-21 Categorical Analysis of Laboratory Tests

Parameter: Urinary Protein

			-		+-		1+		2+		3+		4+		5+	
Group	Time	N	n	%	n	%	n	%	n	%	n	%	n	%	n	%
KLH-2109 200 mg	Screening	48	48	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Run-in	47	38	80.9	5	10.6	3	6.4	0	0.0	1	2.1	0	0.0	0	0.0
	Baseline	48	37	77.1	5	10.4	3	6.3	3	6.3	0	0.0	0	0.0	0	0.0
	Week 4	47	44	93.6	3	6.4	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Week 8	47	44	93.6	3	6.4	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Week 12	46	45	97.8	1	2.2	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	End of Treatment	48	47	97.9	1	2.1	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Follow-up Week 4	48	40	83.3	5	10.4	2	4.2	1	2.1	0	0.0	0	0.0	0	0.0
	End of Follow-up	48	40	83.3	5	10.4	2	4.2	1	2.1	0	0.0	0	0.0	0	0.0
Placebo	Screening	41	39	95.1	2	4.9	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Run-in	41	28	68.3	6	14.6	3	7.3	2	4.9	2	4.9	0	0.0	0	0.0
	Baseline	41	32	78.0	5	12.2	4	9.8	0	0.0	0	0.0	0	0.0	0	0.0
	Week 4	40	34	85.0	5	12.5	0	0.0	1	2.5	0	0.0	0	0.0	0	0.0
	Week 8	39	36	92.3	1	2.6	1	2.6	1	2.6	0	0.0	0	0.0	0	0.0
	Week 12	40	36	90.0	3	7.5	1	2.5	0	0.0	0	0.0	0	0.0	0	0.0
	End of Treatment	41	37	90.2	3	7.3	1	2.4	0	0.0	0	0.0	0	0.0	0	0.0
	Follow-up Week 4	41	36	87.8	4	9.8	0	0.0	1	2.4	0	0.0	0	0.0	0	0.0
	End of Follow-up	41	36	87.8	4	9.8	0	0.0	1	2.4	0	0.0	0	0.0	0	0.0

Table 14.3.1-21 Categorical Analysis of Laboratory Tests

Parameter: Urinary Glucose

			-		+-		1+		2+		3+		4+		5+	
Group	Time	N	n	%	n	%	n	%	n	%	n	%	n	%	n	%
KLH-2109 200 mg	Screening	48	48	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Run-in	47	47	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Baseline	48	48	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Week 4	47	47	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Week 8	47	47	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Week 12	46	46	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	End of Treatment	48	48	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Follow-up Week 4	48	48	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	End of Follow-up	48	48	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Placebo	Screening	41	41	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Run-in	41	41	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Baseline	41	41	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Week 4	40	39	97.5	1	2.5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Week 8	39	39	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Week 12	40	40	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	End of Treatment	41	41	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Follow-up Week 4	41	41	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	End of Follow-up	41	41	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0

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Table 14.3.1-21 Categorical Analysis of Laboratory Tests

Parameter: Urinary Urobilinogen

			-		+-		1+		2+		3+		4+		5+	
Group	Time	N	n	%	n	%	n	%	n	%	n	%	n	%	n	%
KLH-2109 200 mg	Screening	48	0	0.0	48	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Run-in	47	0	0.0	47	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Baseline	48	0	0.0	48	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Week 4	47	0	0.0	47	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Week 8	47	0	0.0	47	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Week 12	46	0	0.0	46	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	End of Treatment	48	0	0.0	48	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Follow-up Week 4	48	0	0.0	48	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	End of Follow-up	48	0	0.0	48	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Placebo	Screening	41	0	0.0	41	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Run-in	41	0	0.0	41	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Baseline	41	0	0.0	41	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Week 4	40	0	0.0	40	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Week 8	39	0	0.0	39	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Week 12	40	0	0.0	40	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	End of Treatment	41	0	0.0	41	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Follow-up Week 4	41	0	0.0	41	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	End of Follow-up	41	0	0.0	41	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0

Table 14.3.1-21 Categorical Analysis of Laboratory Tests

Parameter: Urinary Ketones

			-		+-		1+		2+		3+		4+		5+	
Group	Time	N	n	%	n	%	n	%	n	%	n	%	n	%	n	%
KLH-2109 200 mg	Screening	48	46	95.8	0	0.0	1	2.1	1	2.1	0	0.0	0	0.0	0	0.0
	Run-in	47	44	93.6	0	0.0	3	6.4	0	0.0	0	0.0	0	0.0	0	0.0
	Baseline	48	48	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Week 4	47	47	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Week 8	47	47	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Week 12	46	46	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	End of Treatment	48	48	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Follow-up Week 4	48	46	95.8	0	0.0	2	4.2	0	0.0	0	0.0	0	0.0	0	0.0
	End of Follow-up	48	46	95.8	0	0.0	2	4.2	0	0.0	0	0.0	0	0.0	0	0.0
Placebo	Screening	41	39	95.1	0	0.0	2	4.9	0	0.0	0	0.0	0	0.0	0	0.0
	Run-in	41	39	95.1	0	0.0	1	2.4	1	2.4	0	0.0	0	0.0	0	0.0
	Baseline	41	40	97.6	0	0.0	1	2.4	0	0.0	0	0.0	0	0.0	0	0.0
	Week 4	40	40	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Week 8	39	39	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Week 12	40	39	97.5	0	0.0	1	2.5	0	0.0	0	0.0	0	0.0	0	0.0
	End of Treatment	41	40	97.6	0	0.0	1	2.4	0	0.0	0	0.0	0	0.0	0	0.0
	Follow-up Week 4	41	41	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	End of Follow-up	41	41	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0

Table 14.3.1-22 Vital Signs and Body Weight

Parameter: Systolic Blood Pressure (mmHg)

Group	Time	N	Mean	SD	Min	Q1	Median	Q3	Max
KLH-2109 200 mg	Screening	48	114.6	16.8	89	102	112	122	162
	Run-in	48	114.2	14.8	91	104	114	124	151
	Baseline	48	114.6	15.3	91	103	111	125	159
	Week 4	47	118.4	15.8	97	104	116	128	160
	Week 8	47	114.6	15.6	83	102	114	123	160
	Week 12	46	114.2	15.1	83	103	112	123	154
	End of Treatment	48	114.6	15.0	83	104	113	124	154
	Follow-up Week 4	48	112.4	16.4	84	100	110	125	147
	End of Follow-up	48	112.4	16.4	84	100	110	125	147
Placebo	Screening	41	116.1	15.8	90	103	117	125	162
	Run-in	41	117.6	14.1	93	108	119	125	152
	Baseline	41	115.2	14.5	91	103	115	127	150
	Week 4	40	116.5	15.4	91	106	113	127	166
	Week 8	39	114.3	14.1	79	105	117	125	149
	Week 12	40	118.1	13.7	93	107	118	127	149
	End of Treatment	41	117.7	13.7	93	107	117	126	149
	Follow-up Week 4	41	116.2	13.0	89	107	116	124	143
	End of Follow-up	41	116.2	13.0	89	107	116	124	143

Table 14.3.1-22 Vital Signs and Body Weight

Parameter: Diastolic Blood Pressure (mmHg)

Group	Time	N	Mean	SD	Min	Q1	Median	Q3	Max
KLH-2109 200 mg	Screening	48	72.7	12.3	53	64	72	80	104
	Run-in	48	73.3	11.1	50	66	73	79	102
	Baseline	48	71.7	13.2	50	61	70	82	104
	Week 4	47	74.9	13.0	55	67	74	85	105
	Week 8	47	74.3	11.9	50	65	72	83	103
	Week 12	46	74.1	12.7	52	66	72	82	109
	End of Treatment	48	74.3	12.6	52	66	72	83	109
	Follow-up Week 4	48	69.1	12.3	49	58	69	79	96
	End of Follow-up	48	69.1	12.3	49	58	69	79	96
Placebo	Screening	41	73.0	12.0	51	65	74	81	103
	Run-in	41	74.5	10.1	58	67	73	80	100
	Baseline	41	73.5	11.6	54	63	74	81	99
	Week 4	40	74.1	12.8	50	64	75	84	108
	Week 8	39	73.5	12.5	52	65	73	83	95
	Week 12	40	73.4	12.1	56	63	74	83	106
	End of Treatment	41	73.2	12.0	56	63	73	82	106
	Follow-up Week 4	41	73.0	10.0	57	64	73	80	100
	End of Follow-up	41	73.0	10.0	57	64	73	80	100

Table 14.3.1-22 Vital Signs and Body Weight

Parameter: Pulse Rate (beats/min)

Group	Time	N	Mean	SD	Min	Q1	Median	Q3	Max
KLH-2109 200 mg	Screening	48	73.7	8.4	53	69	75	80	88
	Run-in	48	74.1	10.0	54	69	75	79	105
	Baseline	48	73.5	9.8	52	68	73	80	97
	Week 4	47	73.5	10.7	55	66	73	80	100
	Week 8	47	74.7	10.9	52	66	74	82	98
	Week 12	46	71.7	10.5	51	64	71	81	97
	End of Treatment	48	72.4	10.9	51	64	71	82	97
	Follow-up Week 4	48	74.4	9.4	56	66	74	82	92
	End of Follow-up	48	74.4	9.4	56	66	74	82	92
Placebo	Screening	41	75.4	10.7	56	67	75	80	105
	Run-in	41	75.6	11.4	53	69	75	81	116
	Baseline	41	76.1	11.3	58	70	73	83	105
	Week 4	40	74.9	11.3	52	66	75	81	99
	Week 8	39	74.8	10.3	56	68	73	82	98
	Week 12	40	75.3	9.1	55	69	75	80	97
	End of Treatment	41	75.0	9.2	55	68	74	79	97
	Follow-up Week 4	41	76.3	9.5	58	69	76	83	99
	End of Follow-up	41	76.3	9.5	58	69	76	83	99

Table 14.3.1-22 Vital Signs and Body Weight

Parameter: Temperature (C)

Group	Time	N	Mean	SD	Min	Q1	Median	Q3	Max
KLH-2109 200 mg	Screening	48	36.49	0.44	35.0	36.3	36.6	36.8	37.1
	Run-in	48	36.48	0.33	35.5	36.2	36.6	36.7	37.0
	Baseline	48	36.34	0.41	35.2	36.1	36.4	36.6	37.1
	Week 4	47	36.43	0.38	35.4	36.3	36.6	36.7	37.1
	Week 8	47	36.23	0.39	35.3	35.9	36.3	36.5	37.1
	Week 12	46	36.27	0.45	35.2	36.1	36.4	36.6	37.1
	End of Treatment	48	36.28	0.44	35.2	36.1	36.4	36.6	37.1
	Follow-up Week 4	48	36.40	0.37	35.5	36.2	36.5	36.7	37.1
	End of Follow-up	48	36.40	0.37	35.5	36.2	36.5	36.7	37.1
Placebo	Screening	41	36.42	0.42	35.2	36.3	36.5	36.7	37.3
	Run-in	41	36.41	0.40	35.5	36.2	36.5	36.7	37.0
	Baseline	41	36.33	0.41	35.3	36.1	36.4	36.6	37.1
	Week 4	40	36.34	0.41	35.0	36.2	36.4	36.6	36.9
	Week 8	39	36.37	0.40	35.5	36.2	36.5	36.6	37.0
	Week 12	40	36.33	0.39	35.3	36.1	36.4	36.6	37.1
	End of Treatment	41	36.31	0.39	35.3	36.0	36.4	36.6	37.1
	Follow-up Week 4	41	36.37	0.35	35.6	36.2	36.4	36.6	37.0
	End of Follow-up	41	36.37	0.35	35.6	36.2	36.4	36.6	37.0

Table 14.3.1-22 Vital Signs and Body Weight

Parameter: Weight (kg)

Group	Time	N	Mean	SD	Min	Q1	Median	Q3	Max
KLH-2109 200 mg	Screening	48	60.18	14.40	42.4	53.1	55.9	63.2	114.4
	Run-in	48	60.21	14.39	42.9	53.2	56.2	63.0	116.0
	Baseline	48	60.53	14.49	43.0	53.1	56.2	64.3	114.9
	Week 4	47	59.41	14.79	41.7	51.5	54.9	62.9	114.1
	Week 8	47	58.97	14.85	41.8	51.5	54.8	62.6	113.4
	Week 12	46	58.09	14.51	41.1	51.1	55.1	58.6	112.7
	End of Treatment	48	58.56	14.47	41.1	51.5	55.2	61.1	112.7
	Follow-up Week 4	48	59.99	14.58	42.3	53.0	56.1	63.3	114.2
	End of Follow-up	48	59.99	14.58	42.3	53.0	56.1	63.3	114.2
Placebo	Screening	41	62.26	11.82	43.7	53.3	60.5	70.9	96.1
	Run-in	41	62.23	11.81	44.3	53.1	59.9	71.6	96.0
	Baseline	41	62.20	11.60	43.2	53.2	59.7	70.9	93.9
	Week 4	40	61.91	11.57	43.5	53.3	59.9	71.6	93.9
	Week 8	39	62.18	11.45	43.9	53.1	59.9	72.7	93.2
	Week 12	40	61.97	11.64	43.9	53.5	59.8	71.3	94.5
	End of Treatment	41	62.14	11.54	43.9	53.8	59.8	71.3	94.5
	Follow-up Week 4	41	62.23	11.61	43.6	53.1	60.2	73.1	93.0
	End of Follow-up	41	62.23	11.61	43.6	53.1	60.2	73.1	93.0

Table 14.3.1-23 Change from Baseline in Vital Signs and Body Weight

Parameter: Systolic Blood Pressure (mmHg)

Group	Time	N	Mean	SD	Min	Q1	Median	Q3	Max
KLH-2109 200 mg	Week 4	47	3.5	10.5	-25	-2	5	8	27
	Week 8	47	0.0	8.4	-24	-4	0	6	15
	Week 12	46	0.0	9.2	-20	-6	0	5	22
	End of Treatment	48	0.0	9.0	-20	-6	0	5	22
	Follow-up Week 4	48	-2.2	9.5	-26	-8	-1	6	16
	End of Follow-up	48	-2.2	9.5	-26	-8	-1	6	16
Placebo	Week 4	40	0.7	9.1	-16	-6	1	8	19
	Week 8	39	-1.3	10.3	-25	-7	-2	3	20
	Week 12	40	2.3	9.0	-21	-3	3	8	22
	End of Treatment	41	2.4	9.0	-21	-3	3	10	22
	Follow-up Week 4	41	1.0	10.3	-27	-4	2	8	25
	End of Follow-up	41	1.0	10.3	-27	-4	2	8	25

Table 14.3.1-23 Change from Baseline in Vital Signs and Body Weight

Parameter: Diastolic Blood Pressure (mmHg)

Group	Time	N	Mean	SD	Min	Q1	Median	Q3	Max
KLH-2109 200 mg	Week 4	47	2.9	8.1	-22	-1	3	8	21
	Week 8	47	2.7	7.0	-21	-1	3	8	16
	Week 12	46	2.8	7.9	-19	-2	3	7	19
	End of Treatment	48	2.5	8.0	-19	-2	3	7	19
	Follow-up Week 4	48	-2.6	7.3	-20	-8	-2	2	12
	End of Follow-up	48	-2.6	7.3	-20	-8	-2	2	12
Placebo	Week 4	40	0.2	8.0	-17	-7	1	7	15
	Week 8	39	-0.4	7.6	-13	-5	-1	4	20
	Week 12	40	-0.5	7.4	-15	-7	0	5	17
	End of Treatment	41	-0.3	7.4	-15	-6	0	5	17
	Follow-up Week 4	41	-0.5	8.6	-21	-5	0	3	21
	End of Follow-up	41	-0.5	8.6	-21	-5	0	3	21

Table 14.3.1-23 Change from Baseline in Vital Signs and Body Weight

Parameter: Pulse Rate (beats/min)

Group	Time	N	Mean	SD	Min	Q1	Median	Q3	Max
KLH-2109 200 mg	Week 4	47	-0.2	8.3	-20	-5	0	4	25
	Week 8	47	1.4	8.6	-17	-5	1	6	23
	Week 12	46	-1.5	9.3	-21	-9	-5	3	23
	End of Treatment	48	-1.1	9.4	-21	-9	-4	5	23
	Follow-up Week 4	48	0.9	7.4	-17	-4	1	6	20
	End of Follow-up	48	0.9	7.4	-17	-4	1	6	20
Placebo	Week 4	40	-1.4	8.8	-22	-6	-1	6	15
	Week 8	39	-1.5	10.4	-48	-5	0	5	14
	Week 12	40	-0.9	8.8	-31	-4	1	5	12
	End of Treatment	41	-1.1	8.8	-31	-5	1	4	12
	Follow-up Week 4	41	0.2	9.2	-29	-3	0	6	17
	End of Follow-up	41	0.2	9.2	-29	-3	0	6	17

Table 14.3.1-23 Change from Baseline in Vital Signs and Body Weight

Parameter: Temperature (C)

Group	Time	N	Mean	SD	Min	Q1	Median	Q3	Max
KLH-2109 200 mg	Week 4	47	0.09	0.49	-0.9	-0.2	0.1	0.4	1.6
	Week 8	47	-0.11	0.40	-0.9	-0.4	0.0	0.1	1.1
	Week 12	46	-0.07	0.47	-1.2	-0.3	-0.1	0.1	1.4
	End of Treatment	48	-0.06	0.46	-1.2	-0.3	-0.1	0.1	1.4
	Follow-up Week 4	48	0.07	0.41	-1.4	-0.1	0.1	0.3	0.8
	End of Follow-up	48	0.07	0.41	-1.4	-0.1	0.1	0.3	0.8
Placebo	Week 4	40	0.02	0.38	-0.9	-0.2	0.0	0.2	1.0
	Week 8	39	0.04	0.35	-1.3	-0.1	0.0	0.2	1.0
	Week 12	40	0.00	0.34	-0.6	-0.2	0.0	0.1	1.1
	End of Treatment	41	-0.02	0.36	-0.8	-0.2	0.0	0.1	1.1
	Follow-up Week 4	41	0.04	0.30	-0.5	-0.2	-0.1	0.3	0.8
	End of Follow-up	41	0.04	0.30	-0.5	-0.2	-0.1	0.3	0.8

Table 14.3.1-23 Change from Baseline in Vital Signs and Body Weight

Parameter: Weight (kg)

Group	Time	N	Mean	SD	Min	Q1	Median	Q3	Max
KLH-2109 200 mg	Week 4	47	-1.24	1.70	-10.7	-1.8	-1.1	-0.4	1.2
	Week 8	47	-1.51	2.12	-12.9	-2.1	-1.1	-0.4	0.9
	Week 12	46	-2.05	3.16	-14.0	-2.5	-1.4	-0.4	1.2
	End of Treatment	48	-1.97	3.12	-14.0	-2.4	-1.4	-0.4	1.2
	Follow-up Week 4	48	-0.54	2.08	-11.1	-1.0	-0.3	0.6	2.1
	End of Follow-up	48	-0.54	2.08	-11.1	-1.0	-0.3	0.6	2.1
Placebo	Week 4	40	-0.14	0.74	-1.7	-0.6	0.0	0.4	1.2
	Week 8	39	-0.10	1.12	-2.5	-0.7	-0.1	0.7	2.6
	Week 12	40	-0.08	1.21	-3.1	-0.8	0.2	0.7	2.7
	End of Treatment	41	-0.07	1.20	-3.1	-0.7	0.2	0.7	2.7
	Follow-up Week 4	41	0.02	1.34	-2.8	-0.7	0.2	1.0	2.6
	End of Follow-up	41	0.02	1.34	-2.8	-0.7	0.2	1.0	2.6

Table 14.3.1-24 12-Lead Electrocardiogram Parameters

Parameter: RR Interval (msec)

Group	Time	Measurement Time	N	Mean	SD	Min	Q1	Median	Q3	Max
KLH-2109 200 mg	Screening	---	48	945.3	119.9	779	860	922	1026	1300
	Run-in	---	48	932.1	131.8	689	838	902	1013	1303
	Baseline	Pre-dose	48	942.0	132.4	692	866	930	1000	1401
	Day 1	3 hours post-dose	48	965.6	146.5	711	839	945	1062	1434
	Week 4	Pre-dose	47	960.0	134.9	722	875	952	1052	1274
	Week 8	Pre-dose	47	963.1	132.8	750	858	971	1052	1333
	Week 12	---	46	984.4	154.5	736	869	971	1071	1419
	End of Treatment	---	48	977.9	154.6	736	857	968	1065	1419
	Follow-up Week 4	---	48	948.9	129.6	720	851	952	1030	1292
	End of Follow-up	---	48	948.9	129.6	720	851	952	1030	1292
Placebo	Screening	---	41	942.3	116.4	659	871	923	1000	1194
	Run-in	---	41	940.2	132.5	625	869	930	1000	1304
	Baseline	Pre-dose	41	928.4	126.5	681	833	942	1016	1176
	Day 1	3 hours post-dose	41	951.9	141.7	689	864	942	1034	1224
	Week 4	Pre-dose	40	926.3	128.2	668	827	907	1004	1224
	Week 8	Pre-dose	39	910.3	134.5	704	826	869	985	1250
	Week 12	---	40	932.6	114.3	697	857	926	1014	1200
	End of Treatment	---	41	933.1	112.9	697	857	928	1000	1200
	Follow-up Week 4	---	41	910.0	101.6	722	838	909	967	1132
	End of Follow-up	---	41	910.0	101.6	722	838	909	967	1132

Table 14.3.1-24 12-Lead Electrocardiogram Parameters

Parameter: PR Interval (msec)

Group	Time	Measurement Time	N	Mean	SD	Min	Q1	Median	Q3	Max
KLH-2109 200 mg	Screening	---	48	158.2	16.9	124	146	159	168	206
	Run-in	---	48	157.7	17.2	124	146	156	168	206
	Baseline	Pre-dose	48	157.6	17.8	125	142	157	170	224
	Day 1	3 hours post-dose	48	155.0	20.2	90	142	156	169	215
	Week 4	Pre-dose	47	154.1	17.1	118	142	153	166	199
	Week 8	Pre-dose	47	155.6	17.5	120	144	155	166	202
	Week 12	---	46	155.7	17.3	126	145	156	164	203
	End of Treatment	---	48	156.9	17.9	126	146	157	169	203
	Follow-up Week 4	---	48	155.6	15.9	120	143	155	169	198
	End of Follow-up	---	48	155.6	15.9	120	143	155	169	198
Placebo	Screening	---	41	162.0	24.4	112	148	158	173	230
	Run-in	---	41	160.8	23.9	102	146	160	173	224
	Baseline	Pre-dose	41	160.0	26.4	76	147	161	172	228
	Day 1	3 hours post-dose	41	159.3	26.4	87	146	160	169	246
	Week 4	Pre-dose	40	164.2	24.0	116	150	159	184	212
	Week 8	Pre-dose	39	163.1	22.1	120	145	162	179	220
	Week 12	---	40	161.8	25.6	110	147	158	177	232
	End of Treatment	---	41	161.3	25.4	110	145	158	176	232
	Follow-up Week 4	---	41	161.3	23.1	112	148	160	176	222
	End of Follow-up	---	41	161.3	23.1	112	148	160	176	222

Table 14.3.1-24 12-Lead Electrocardiogram Parameters

Parameter: QRS Duration (msec)

Group	Time	Measurement Time	N	Mean	SD	Min	Q1	Median	Q3	Max
KLH-2109 200 mg	Screening	---	48	88.9	8.8	72	83	89	96	110
	Run-in	---	48	88.8	9.4	74	82	89	95	110
	Baseline	Pre-dose	48	87.6	9.3	70	81	88	94	106
	Day 1	3 hours post-dose	48	89.6	12.4	72	82	89	95	148
	Week 4	Pre-dose	47	89.7	8.7	74	84	90	96	110
	Week 8	Pre-dose	47	89.7	9.7	72	82	90	96	109
	Week 12	---	46	90.0	8.5	74	82	90	96	108
	End of Treatment	---	48	90.1	8.4	74	83	90	96	108
	Follow-up Week 4	---	48	88.8	9.4	72	82	89	97	106
	End of Follow-up	---	48	88.8	9.4	72	82	89	97	106
Placebo	Screening	---	41	88.6	8.7	72	84	87	94	110
	Run-in	---	41	88.2	9.3	74	81	86	98	109
	Baseline	Pre-dose	41	90.1	17.3	74	83	86	94	188
	Day 1	3 hours post-dose	41	90.0	16.7	48	82	88	96	174
	Week 4	Pre-dose	40	87.7	8.2	74	83	85	93	108
	Week 8	Pre-dose	39	88.8	8.0	76	82	88	94	108
	Week 12	---	40	89.0	8.3	74	84	87	96	107
	End of Treatment	---	41	89.1	8.2	74	84	88	96	107
	Follow-up Week 4	---	41	88.3	9.0	72	82	86	96	107
	End of Follow-up	---	41	88.3	9.0	72	82	86	96	107

Table 14.3.1-24 12-Lead Electrocardiogram Parameters

Parameter: QT Interval (msec)

Group	Time	Measurement Time	N	Mean	SD	Min	Q1	Median	Q3	Max
KLH-2109 200 mg	Screening	---	48	410.3	23.3	368	394	406	421	473
	Run-in	---	48	412.1	24.7	374	394	409	425	466
	Baseline	Pre-dose	48	412.6	27.5	370	388	410	429	484
	Day 1	3 hours post-dose	48	425.8	30.1	366	404	422	448	498
	Week 4	Pre-dose	47	416.1	27.6	362	396	414	440	469
	Week 8	Pre-dose	47	416.9	24.9	374	399	414	432	484
	Week 12	---	46	422.4	27.6	362	400	420	438	485
	End of Treatment	---	48	421.0	27.9	362	400	418	437	485
	Follow-up Week 4	---	48	410.0	27.2	354	390	406	429	468
	End of Follow-up	---	48	410.0	27.2	354	390	406	429	468
Placebo	Screening	---	41	411.0	28.4	344	394	415	426	482
	Run-in	---	41	413.6	28.1	346	394	414	434	476
	Baseline	Pre-dose	41	410.8	27.5	358	390	408	420	492
	Day 1	3 hours post-dose	41	416.5	31.7	364	398	414	430	498
	Week 4	Pre-dose	40	410.0	26.7	358	391	410	425	474
	Week 8	Pre-dose	39	408.3	30.0	356	391	403	427	490
	Week 12	---	40	410.7	24.8	350	398	408	425	474
	End of Treatment	---	41	410.3	24.6	350	398	407	424	474
	Follow-up Week 4	---	41	407.0	26.6	360	386	410	422	468
	End of Follow-up	---	41	407.0	26.6	360	386	410	422	468

Table 14.3.1-24 12-Lead Electrocardiogram Parameters

Parameter: Heart Rate (beats/min)

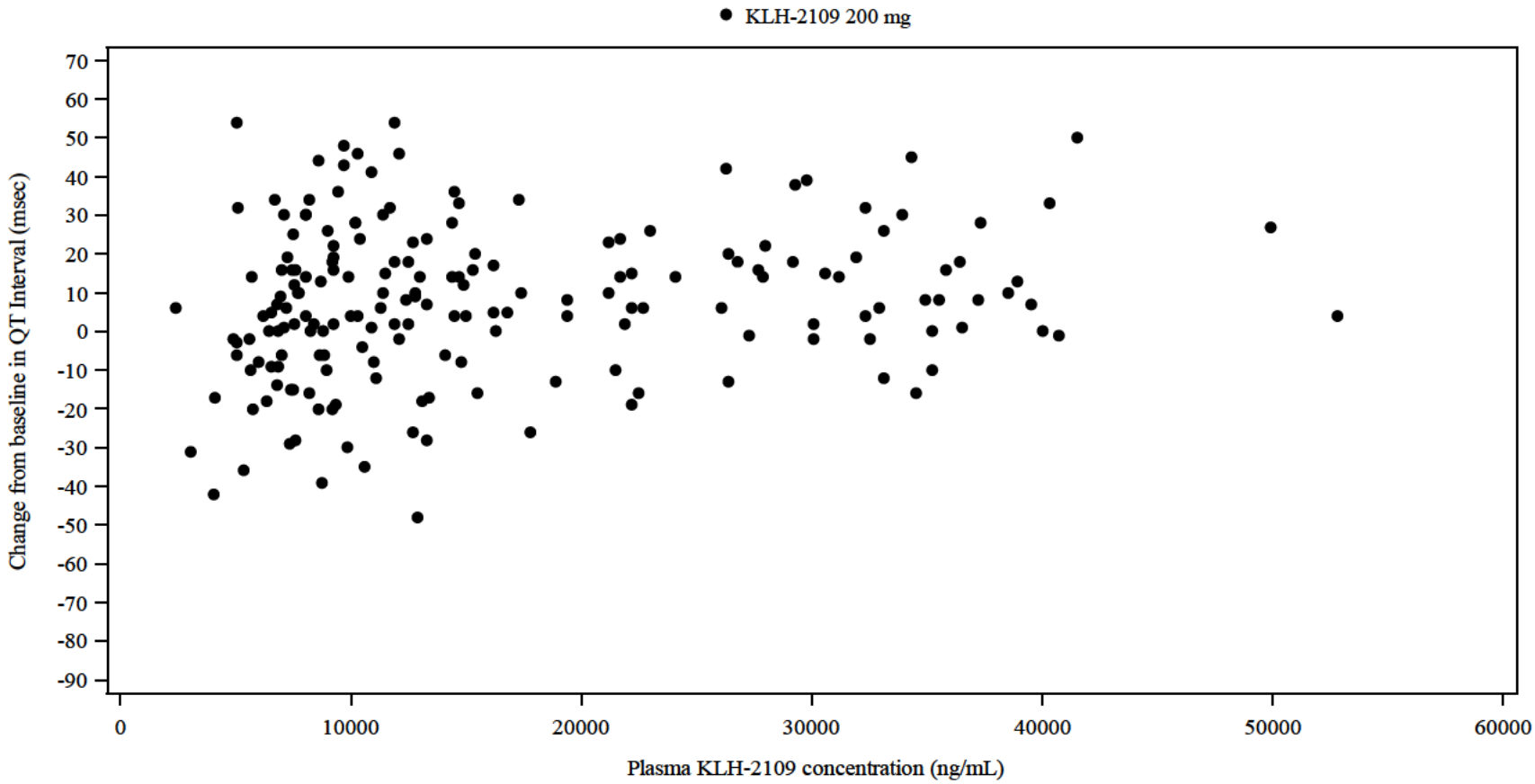
Group	Time	Measurement Time	N	Mean	SD	Min	Q1	Median	Q3	Max
KLH-2109 200 mg	Screening	---	48	64.4	7.5	46	59	65	70	77
	Run-in	---	48	65.6	8.9	46	60	67	72	87
	Baseline	Pre-dose	48	64.9	8.8	42	60	65	69	87
	Day 1	3 hours post-dose	48	63.5	9.2	41	57	64	72	84
	Week 4	Pre-dose	47	63.7	9.0	47	57	63	69	83
	Week 8	Pre-dose	47	63.4	8.5	45	57	62	70	80
	Week 12	---	46	62.4	9.5	42	56	62	69	82
	End of Treatment	---	48	62.8	9.5	42	57	62	70	82
	Follow-up Week 4	---	48	64.4	8.9	46	58	63	71	83
	End of Follow-up	---	48	64.4	8.9	46	58	63	71	83
Placebo	Screening	---	41	64.6	8.3	50	60	65	69	91
	Run-in	---	41	65.1	9.5	46	60	65	69	96
	Baseline	Pre-dose	41	65.8	9.1	51	59	64	72	88
	Day 1	3 hours post-dose	41	64.4	9.7	49	58	64	69	87
	Week 4	Pre-dose	40	66.0	8.8	49	60	67	73	90
	Week 8	Pre-dose	39	67.2	9.3	48	61	69	73	85
	Week 12	---	40	65.0	8.0	50	59	65	70	86
	End of Treatment	---	41	65.0	8.0	50	60	64	70	86
	Follow-up Week 4	---	41	66.7	7.5	53	62	66	72	83
	End of Follow-up	---	41	66.7	7.5	53	62	66	72	83

Table 14.3.1-24 12-Lead Electrocardiogram Parameters

Parameter: QTcF Interval (msec)

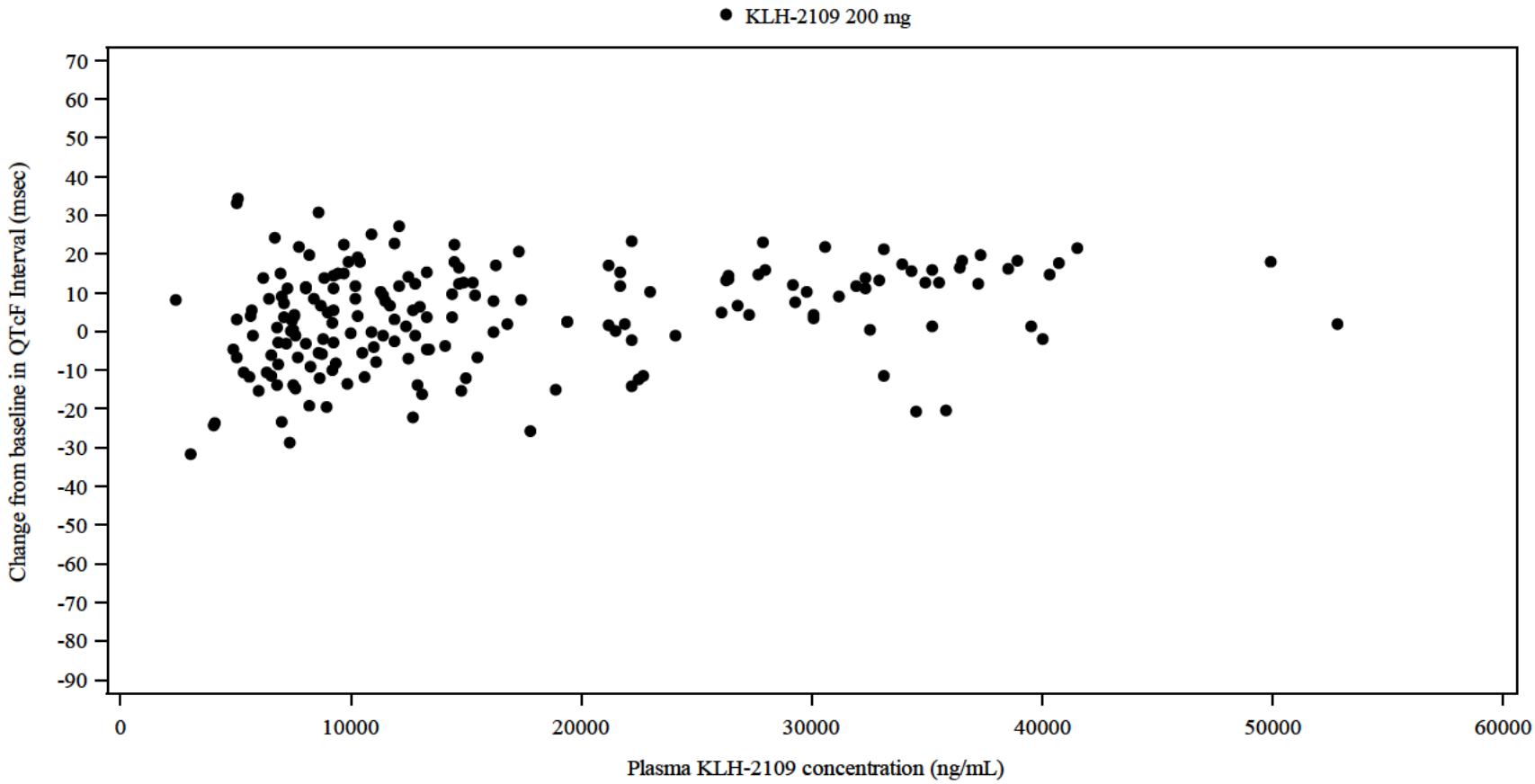
Group	Time	Measurement Time	N	Mean	SD	Min	Q1	Median	Q3	Max
KLH-2109 200 mg	Screening	---	48	418.6	13.9	391	409	419	427	460
	Run-in	---	48	422.6	13.6	398	412	424	432	463
	Baseline	Pre-dose	48	421.5	16.8	388	409	425	433	456
	Day 1	3 hours post-dose	48	431.6	17.2	404	417	432	443	471
	Week 4	Pre-dose	47	422.4	14.5	400	409	422	431	468
	Week 8	Pre-dose	47	422.9	13.2	396	415	421	431	468
	Week 12	---	46	425.6	14.5	400	415	425	433	469
	End of Treatment	---	48	425.1	14.7	400	415	425	432	469
	Follow-up Week 4	---	48	417.9	17.8	384	407	417	427	469
	End of Follow-up	---	48	417.9	17.8	384	407	417	427	469
Placebo	Screening	---	41	419.5	17.6	379	409	417	431	455
	Run-in	---	41	422.8	16.5	387	411	422	435	460
	Baseline	Pre-dose	41	421.6	15.7	396	412	420	431	466
	Day 1	3 hours post-dose	41	424.1	18.8	388	412	420	434	472
	Week 4	Pre-dose	40	421.1	14.6	389	412	419	432	451
	Week 8	Pre-dose	39	421.8	17.0	377	409	423	434	455
	Week 12	---	40	420.8	14.8	383	413	422	427	449
	End of Treatment	---	41	420.3	14.9	383	413	421	427	449
	Follow-up Week 4	---	41	420.2	18.4	375	409	422	434	464
	End of Follow-up	---	41	420.2	18.4	375	409	422	434	464

Figure 14.3.1-1 Scatter Plot of Change from Baseline in QT versus Plasma KLH-2109 Concentrations



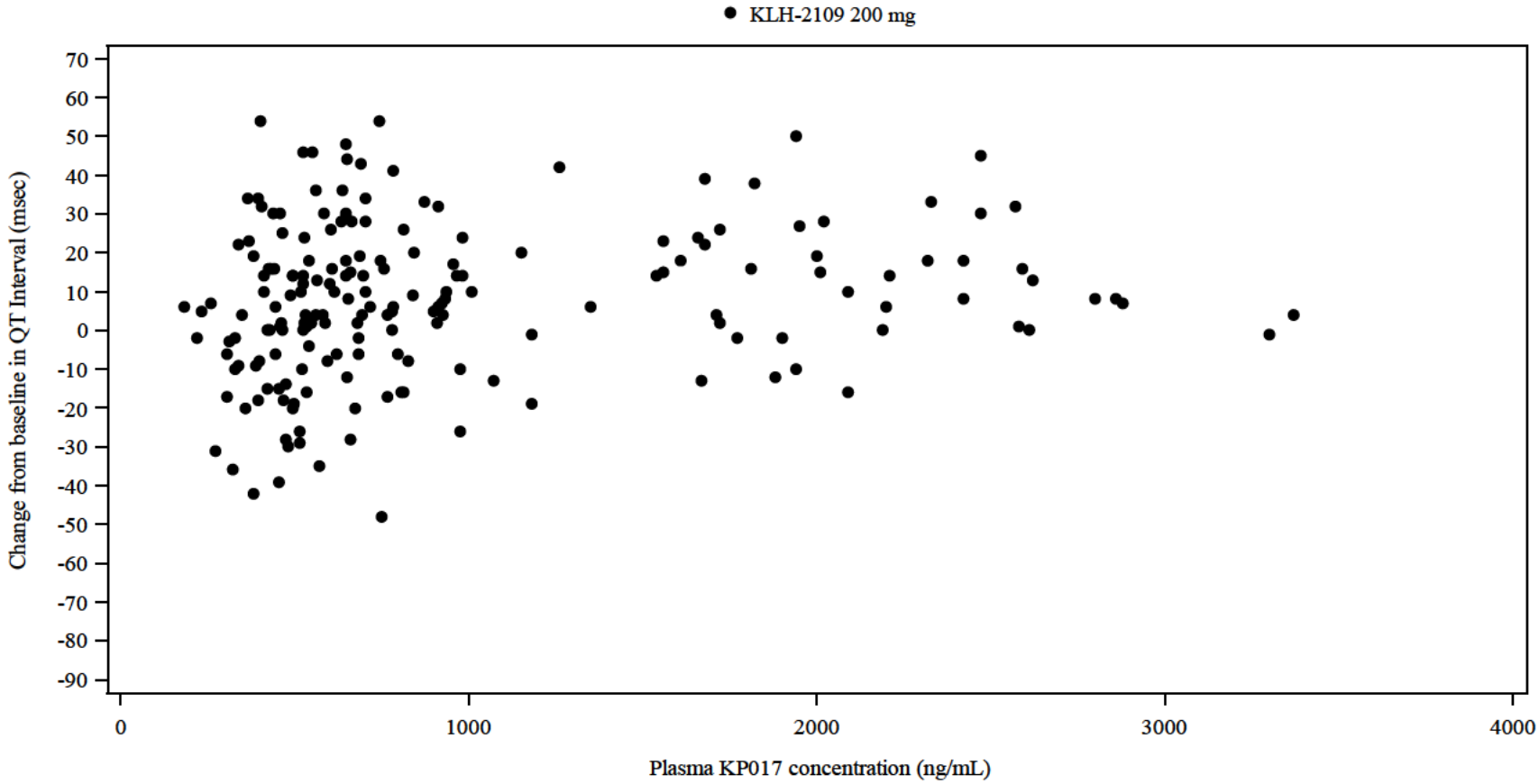
Run Date: 2024-09-13 11:18

Figure 14.3.1-2 Scatter Plot of Change from Baseline in QTcF versus Plasma KLH-2109 Concentrations



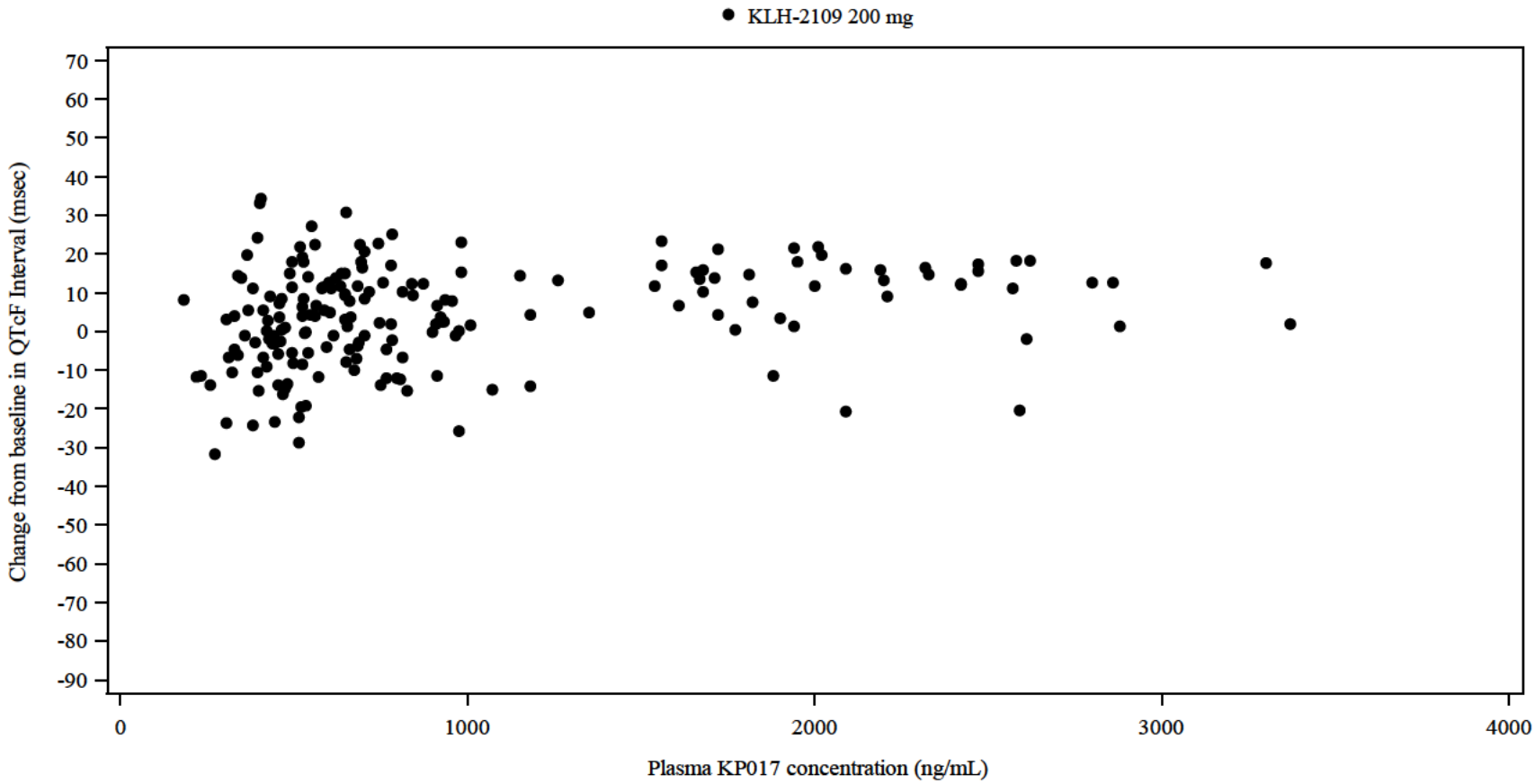
Run Date: 2024-09-13 11:18

Figure 14.3.1-3 Scatter Plot of Change from Baseline in QT versus Plasma KP017 Concentrations



Run Date: 2024-09-13 11:18

Figure 14.3.1-4 Scatter Plot of Change from Baseline in QTcF versus Plasma KP017 Concentrations



Run Date: 2024-09-13 11:18

2.7.5 参考文献

2.7.2.5、2.7.3.6、2.7.4.7、2.7.6.6、2.7.6.8、2.7.6.11、2.7.6.12 及び 2.7.6.14 参照